DENTAL RESTORATION SURVIVAL
PATIENT OR DENTIST, WHO IS KEY?

MARK LASKE

Dental restoration surival. Patient or dentist, who is key?

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Chapter 1

General introduction

General introduction

Repair of dental tissue loss, with the aim of restoring the functional, aesthetic and bio-mechanical properties of a tooth, is one of the common daily activities a general dental practitioner (GDP) undertakes. However, there is a wide range of techniques and materials which can be used. A distinction is made between direct and indirect restorative methods. The direct technique, in which the dental preparation is performed and the subsequent restoration fabricated, intraorally in a single session, is most frequently used in contemporary dentistry. The indirect method normally requires multiple sessions and most importantly, the restoration is fabricated outside the mouth.

In recent decades, restorative materials have been modified and improved significantly. These advances were driven by the demands for an aesthetically pleasing, tooth coloured restorative material as a substitute for amalgam and metal based indirect restorations. Traditionally, indirect restorations were fabricated using metal-ceramics or gold, while nowadays polycrystalline oxide ceramics and glass ceramics are more frequently used.

The first composite resin restorative materials in dentistry were introduced in the 1950s, and their properties are being constantly modified [1]. Fracture, discoloration, risk of secondary caries and low abrasion resistance were the major disadvantages associated with the early resin materials; but these issues have been addressed since the 1990s [2]. In addition to their aesthetic properties, resin based materials possess adhesive properties which led to reduced preparation and greater conservation of tooth structure; particularly compared to amalgam which is macro-mechanically retained. As a result, the placement of tooth-coloured restorative materials is now standard procedure in the anterior as well as posterior teeth [2].

Although composite resin, amalgam and indirect restorations have all been used for posterior restorations for many years, there is paucity in controlled and randomized clinical trials comparing survival rates of these different restorative materials. In most of the survival studies, a limited number of restorations is placed according to a fixed protocol and evaluated by calibrated practitioners. This study design enables an unbiased comparison of different restorative materials in detail, where restorations are evaluated by specified criteria such as FDI [3] or USPHS criteria [4]. Survival rates of restorations in these prospective studies, often designed to evaluate new materials, are high [5]. However, results from studies using this design cannot be directly translated to daily routine practice. Clinical research conducted using general dental practitioners in primary care requires different study designs.

Study design of survival studies

Performance of dental restorations expressed in survival rates, can be considered as a possible indicator for the quality of care delivered. Systematic reviews on posterior restoration performance, show Annual Failure Rates (AFRs) varying between 1 and 4% [5-9]. These reviews are mostly based on prospectively designed clinical trials carried out in university settings and often have low power and short follow up due to the constraints of the setting. Moreover, due to the detailed criteria used for assessing the clinical quality of restorations [4] independent assessor may assess restorations as failed based on findings such as 'severe discoloration of margins' or 'exposed dentine surface'. Even though these restorations are still functioning well for the patient and may continue to do so for several years, and would not need to qualify as failed in clinical care. In this way the strict research criteria may lead to an underestimation of expected performance in a care setting.

An alternative approach is to use practice based studies, where longevity analysis is based on the patient record. Failed restorations are those that the GDP has decided to replace [10] while sometimes an independent researcher assesses the endpoint of the restoration [11, 12]. Until recently the number of longitudinal studies on the longevity of restorations placed by general dental practitioners (GDPs) was limited to these studies, and related to selective dental practices. Other longitudinal studies were based on public health care settings in Scandinavian adolescents [13, 14]. These practice based studies showed AFRs varying from 1.6% to 2.9% and revealed the influence of the patients' caries risk and bruxing behaviour as significant risk factors for the survival of restorations. In order to extrapolate on these practice based findings, several longitudinal analyses have been performed based on data from the United Kingdom's NHS (National Health Service) insurance database [15-18], but larger databases based on patient files from GDPs were not available.

Practice based studies investigating restoration survival rates present considerable indication bias from general practitioners, furthermore, restorative procedures are not well controlled. This is unavoidable when investigating real world dentistry. Analyses of this kind present potentially many pitfalls due to confounding risk factors therefore demanding a multi-variable model to evaluate the survival of restorations.

In the Netherlands, GDPs generally have a large group of listed patients who are loyal to the practice and regularly attend for assessment and maintenance over a prolonged period of time. Moreover, in most practices, electronic patient files are available which provide information on the placement, replacement and censoring date (last check-up) of all restorations placed by the GDP. This offers a unique opportunity to investigate the longevity of restorations placed by a large group of dentists objectively. To obtain this data, the Practice Based Research Network Nijmegen (PBRN) was founded in 2012.

Risk factors for restoration failure

University based prospective studies showed the potential performance of restorations under ideal conditions [5]. Their results also suggested that material properties were less important than previously presumed. In practice based studies, many risk factors on different levels are likely to be present and can therefore be investigated. As ideal conditions are not always realistically plausible in general practice, studies showing the performance of restorations under the full spectrum of routine care conditions, are needed to assess the quality and possibilities of restorative dentistry in everyday practice. [9, 19, 20].

Risk factors may be present at the practice/operator level, the patient level and the tooth/restoration level. On the practice/operator level, factors such as age, gender, and experience level have been investigated. The effect of patients changing dentists has also been demonstrated to be significant [18]. Although the evidence is limited, the operator can be assumed to play a major role in restoration performance [7, 21].

Patient level risk factors include gender, age and individual characteristics, such as caries risk or bruxism [9, 16, 20]. Additionally, socio-economic status has been shown to be associated with risk of failure [22]. Systematic reviews including patient related risk factors show that their influence on restoration performance is not only significant, but also relevant, with Hazard ratios ranging from 2.5 up to 8.3 [9, 23].

On the tooth/restoration level, tooth type, size of the restoration as well as the type of restorative material may play a role. A higher rate survival of restorations in premolars compared to molars has been reported in some studies [17, 24], but not confirmed by others [25]. Several studies showed a lower survival rate for larger restorations [12, 17], but again this was not always confirmed [24, 25].

To improve patient dental care, it is necessary to identify possible risk factors for the failure of restorations. Reports have been published using larger sample sizes [26, 27]; however these studies are hampered by their retrospective nature and their failure to include potential restoration performance risk factors. GDPs did not include these factors in the patient files and so they could not be analysed. With the growing tendency towards more personalized care in dentistry [28] and the public demand for transparency and shared decision making [29], there is an increased need for GDPs to expand the information stored in the patient files which are nowadays mostly electronic. These electronic patient files (EPFs) offer the opportunity to identify and assess risk factors on patient level in a standardized way. Patients' general health, periodontal status, caries risk and risk for parafunctional habits can be documented to aid treatment planning. For research purposes, these risk factors are indispensible to providing a reliable analysis of restoration survival in private practice.

Methodology in survival studies

Studies evaluating restorations placed by general practitioners, often consider a new intervention on a specific previous restoration as a failure of the original restoration [10, 30]. This is dependent on the clinical judgement of either the dentist who placed the restoration, or a new operator and will vary among dentists [31]. For studies based on insurance data, a new intervention on the same tooth will be defined as failure [26, 27]. However, a new restoration is not necessarily related to the previously placed one. These differences in 'endpoints' for longevity analysis may influence the outcome.

Currently, repair instead of replacement is considered a preferable treatment option when a restorative intervention is required [32]. Repair has been proven to increase restoration survival [33-36], which would indicate that it should not be considered as a failure in the analysis. The same is applicable for restorations placed due to endodontic treatments which should not normally be considered as a failure related to the restoration. Anusavice described these conflicting phenomena for indirect restorations, where the particularly distinct terminology of 'chipping' and performed endodontic treatments complicated the classification of success and failure of crown and bridge restorations [37]. For indirect restorations, he described three categories: success (no intervention on the placed restoration), survival (restoration still in place and functioning, but repaired or endodontically treated) and failure (restoration replaced or tooth extracted). For direct restorations these criteria of success, survival and failure are not commonly used and so there is need for standardization of terminology in order to compare the outcomes of longevity studies.

Dental caries and decision making

The incidence of dental caries has decreased over the past few decades, but it remains one of the most prevalent diseases worldwide and is a major reason for restorative treatment in private practice [38]. Consequently, caries management is a prominent issue in oral healthcare. Prior to the late 1970s, caries progression in dentine was considered to be a rapid and irreversible process and the concept of arresting caries lesions wasn't well adopted yet [39]. In the early 1980s, the first studies showing caries to be a slowly progressive disease which needed a more preventive, non-operative concept for its treatment, were published [40, 41]. Nowadays, it is commonly accepted that a low-cariogenic diet, adequate oral hygiene and fluoride can control or arrest the progression of caries lesions [42]. As a result, an increased emphasis is placed on the concept that caries should be managed using non-invasive, preventive methods, as much as possible [39, 43]. Absence or failure of preventive management, will lead to the need for operative intervention. A minimally invasive treatment concept for caries lesions has been advocated in recent history. This consists of postponing the moment of intervention [44] and when intervening, making smaller preparations restricted to removal of carious tissue only, instead of the 'extension for prevention' treatment concept previously adopted. With regards to replacing existing restorations, the concept has changed from 'replace when in doubt' towards a more conservative approach of monitoring, refurbishing and repairing, with replacing as a last resort alternative [45]. As mentioned before, the decision for the GDP to intervene hinges on many factors and varies amongst practitioners [31]. As a result, it may considerably impact on the survival of restorations in general practice. Although the evidence is lacking, the need for further investigation of dentists' treatment decisions seems obvious.

The decision to treat a caries lesion operatively is based on diagnosis by visual and tactile inspection for occlusal caries, while bitewing radiography is mainly employed for diagnosis of approximal caries [46-48]. Based on the presence of discoloured or cavitated fissures and translucencies on radiographs, dentists decide when and how to treat a caries lesion. Espelid and Tveit [49, 50] developed questionnaires to investigate dental restorative treatment thresholds and strategies employed in several countries. This showed a wide variation in outcomes [51]. This variation raises the hypothesis that dentists may be divided into types or profiles as being proactive: i.e. more eager to replace in an attempt to prevent complications, or reactive: postponing interventions until a complication occurs and patients ask for help. It can be supposed that operator profiles have an influence on potential dental overtreatment and subsequently restoration survival. There seems to be a tendency towards a more minimally invasive strategy for the treatment of primary caries lesions, but this has not been established yet. Outcomes from the surveys can be compared over time, and if possible within countries, as patterns may be different around the world.

Aim of the PhD research

Dental restoration survival within general dental practice depends on a wide range of factors; not only tooth and restoration related factors which have already been examined in depth, but also dentist and patient-related factors. The extent to which each of these factors contributes to restoration survival is as of yet undetermined. A large database from the EPFs of general practitioners in the PBR network enables us to carry out further research with regards to factors affecting restoration survival in general practice.

The overall aim of this thesis is to investigate the influence of possible risk factors at the practice/dentist level, the patient level and the tooth/restoration level on longevity of direct dental restorations.

These specific research aims can be listed as:

1. Investigate the longevity of direct restorations placed by a large group of GDPs and explore the effect of practice/operator, patient, and tooth/restoration related factors on restoration survival in a long-term retrospective practice-based study (Chapter 2).

2. Investigate the influence of possible risk factors on practice, patient, tooth and restoration level on longevity of direct class II restorations in a long-term retrospective practice-based study (Chapter 3) and prospective cohort study (Chapter 4).

3. Investigate the influence of using different endpoint definitions and inclusion criteria in longevity analysis on the outcome expressed in Annual Failure Rate (Chapter 5).

4. Investigate decision making aspects of dentists to see if worldwide trends exist towards a more conservative minimally invasive treatment concept for primary caries restorative intervention, as measured by treatment thresholds and the choice of restorative techniques made by dentists (Chapter 6).

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Chapter 2

Longevity of direct restorations in Dutch dental practices. Descriptive study out of a practice based research network

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Abstract

The aim of this retrospective practice-based study was to investigate the longevity of direct restorations placed by a group of general dental practitioners (GDPs) and to explore the effect of practice/operator, patient, and tooth/restoration related factors on restoration survival. Electronic Patient Files of 24 general dental practices were used for collecting the data for this study. From the patient files, longevity of 359,548 composite, amalgam, glass-ionomer and compomer placed in 75,556 patients by 67 GDPs between 1996 and 2011 were analysed. Survival was calculated from Kaplan-Meier statistics. A wide variation in annual failure rate (AFR) exists between the different dental practices varying between 2.3% and 7.9%. Restorations in elderly people (65 years and older, AFR 6.9%) showed a shorter survival compared to restorations placed in patients younger than 65 years old (AFR 4.2%-5.0%). Restorations in molar teeth, multi-surface restorations and restorations placed in endodontically treated teeth seemed to be more at risk for re-intervention. The investigated group of GDPs place restorations with a satisfactory longevity (mean AFR 4.6% over 10 years), although substantial differences in outcome between practitioners exist. Several potential risk factors on practice/operator, patient, and tooth/restoration level have been identified and require further multi variable investigation.

Introduction

Placing and replacing of restorations is the main work of most general dental practitioners (GDPs). The longevity of the restorations can be seen as an indicator for the quality of care delivered. Factors that have been identified as affecting the restoration performance are the filling material and their properties [1] as well as the dental piece itself and the patient (e.g. socio-economic status caries risk) and dentist characteristics (e.g. experience) [2]. The results of these reviews are however rather inconclusive.

Some studies found a better performance of amalgam restorations compared to other restorative materials, [3-7] while others showed a comparable survival of composite and amalgam restorations [8, 9]. An increased number of restoration surfaces was shown to result in a higher re-intervention rate [10], and molar teeth and endodontically treated teeth have been reported to have a higher risk for early re-intervention [5].

Socioeconomic status of the patient has been shown to affect the longevity of restorations [11], probably because the prevalence of dental caries is associated with social determinants [12, 13]. Also the influence of caries risk of patients on restoration longevity has been demonstrated [8, 14]. With respect to age and gender, some studies reported that restorations in older patients and male patients have a lower survival [15], while other studies failed to demonstrate this effect [14].

A paper from the UK, based on an insurance dataset showed that operator and practice related factors, notably changing dentists, influenced the longevity of restorations [16]. Another study, comparing different types of indirect restorations demonstrated a clear operator effect on survival [17]. However, the influence of the dentist on the results is not always obvious [18, 19], as was also shown in the review of Beck et al. Overall, this is the level least investigated. This is not surprising, as most scientific research is not carried out in general dental practice, and if it is, it is not common that many operators are included and taken into account as a factor.

The number of longitudinal studies on longevity of restorations placed by GDPs is limited to studies related to isolated dental practices [8, 20, 21] and public health care in Scandinavian adolescents [22, 23]. On a larger scale, several longitudinal analyses have been made based on data from the NHS insurance database in the UK [5, 15, 16, 24], but larger databases from GDPs have not been analyzed yet. Therefore there is need for a longitudinal practice based study, with at least a 5 year follow up time, and a multi factorial approach.

In the Netherlands, dentists generally have a large group of listed patients who are loyal to the practice and show up regularly for checkups over a longer period of time. Moreover, most practices have electronic patient files. This offers the unique opportunity to investigate the longevity of restorations placed by a large group of dentists.

The aim of this retrospective practice-based study is to investigate the longevity of direct restorations placed by a large group of GDPs and to explore the effect of practice/operator, patient, and tooth/restoration related factors on restoration survival.

Materials and Methods

Inclusion and data collection

General practices were recruited from the Nijmegen dental practice based research network. Within these practices, all individual dentists were included that contributed with a minimum of 300 restorations. Within these practices, all patients were included that visited the practices for regular checkups. Data from all direct restorations placed in permanent teeth in the years 1996 to 2011 were collected from the Electronic Patient Files (EPF) of the patients. Restorations with missing variables and uncertainties were excluded from the dataset. Design and protocol were approved by the local ethics committee, METC (CMO file nr. 2013/483). Data were digitally extracted, rendered anonymous and sent to the research group by the dentists using an application designed by the two involved software firms that provided the EPF software (Exquise®, Kwadijk, NL, starting 1999; Complan®, Heerhugowaard, NL, starting 1996). The application transformed all data on the placed direct restorations into Excel data files.

Outcome parameters

From all direct restorations, dates of restoration placement, last check-up visit of the patient and dates of re-intervention were recorded. The restoration was considered as failed if a restoration was replaced or repaired, the tooth was extracted, or in case of an endodontic or prosthetic treatment. Replacement or repair was defined as an intervention when a new restoration was placed in the same tooth and one or more surfaces already involved in the previous restoration. An exception was made for mesial-occlusal (MO) and distal-occlusal (DO) class II restorations in molars and premolars. When a MO restoration was placed as the first restoration and the intervention treatment was a DO restoration, analysis for the initial restoration was censored, because many MO and DO restorations in posterior teeth are two independent (box type) restorations, and it would not be appropriate to qualify them all as failed. In anterior teeth, the same exception was made

for DB/MB and DP/MP class III restorations. When no intervention was performed on the teeth during the evaluation period, and the tooth was still in function at the last check-up visit, the restoration was considered as successful and censored at that date.

Independent variables

On the practice level the following variables were recorded: urban (towns with >40.00 inhabitants) or rural location, practice type (solo, small (2 or 3 dentists) or larger group (>3 dentists)), practice size (small; placing <1,000 restorations per year, larger; placing >1,000 restorations per year) deprived working area (based on practice ZIP-codes and a standard conversion table provided by the Dutch Central Office of Statistics), and experience expressed by the year of graduation of the GPDs (graduated before 1981; graduated between 1981 and 1990 and graduated in 1991 or later).

On a patient level, gender, age and the presence of a removable denture were recorded. Regarding age, patients were divided into 5 groups; 5-15 years (children), 16-25 years (adolescents), 26-45 years (young adults), 46-65 years (adults) and 66-95 years (elderly). Removable denture presence was grouped into three categories: no denture present, partial denture present, and full denture present in opposing jaw.

On the tooth/restoration level tooth number (FDI system), number of included restored surfaces (1, 2, 3, ≥4), applied restorative materials (amalgam, composite, glass-ionomer and compomer) and whether a tooth was endodontically treated (yes/no), was recorded. Subgroups were made by quadrants, jaw (upper/lower), tooth group (anterior, premolar, molar) and tooth number in the arch (1 to 8).

Statistical analysis

Statistical analyses were performed with SPSS 20. To explore the effect of variables on longevity, Kaplan Meier analyses were used to create survival tables and curves. Out of the survival tables, mean Annual Failure Rate (AFR) over 10 years was calculated according to the formula: $AFR_{10}(\%) = 1 - \sqrt[10]{x}^{*}\ 100$, in which 'x' level of survival. As most patients in the study contributed with multiple restorations, the method described by Chuang et al. [25], to produce statistically valid standard errors for the estimates of survival, was performed.

The composition of the dataset dealing with different types of restorations, notably anterior and posterior restorations, rendered statistical testing of perceived effects of independent variables, using log-rank tests or multi variable analysis like a cox-regression, unsuitable. Such analyses will be performed at a later stage on more homogeneous subgroups and reported separately.

Results

Table 1 shows a description of the study population. Twenty four dental practices were included in the study, with 67 dental practitioners who met the inclusion criterion of 300 contributing restorations. No dental practices were excluded. A total of 359,548 anterior and posterior restorations were included in the study. The restorations were placed in 75,556 patients, 36,351 male and 39,205 female (aged between 5 and 95 years). The mean number of included restorations per patient was 4.8. Follow up differed between 3.75 and 15 years.

Practice/operator related factors

Tables 2 and 3 summarize the results of the practice related factors. Overall restoration survival varied widely between the 24 practices. The lowest restoration AFR over 10 years (2.3%), was less than third of the practice with the highest AFR (7.9%) (Table 2). Differences in AFR were observed between the different types of the practice, the AFR of restorations placed in solo or small group practices (2 or 3 dentists) was lower compared to that in larger group practices. The size of the practice seemed not to influence the longevity, showing a comparable AFR. Restorations placed in a practice in an area with a low SES showed a higher AFR, urban and rural practices showed comparable AFR. The year of graduation of the dentist seemed to influence restoration longevity, with a higher AFR of restorations placed by less experienced GDPs.

Table 1. Description of study population

	N restorations	N practices/operators
Practice characteristics, N=24 practices, N= 67 operators		
Location		
Urban	211,605	12
Rural	147,943	12
Type of practice		
Solo	81,351	8
Small group, 2-3 dentists	184,798	12
Larger group, more than 3 dentists	93,399	4
Practice size		
Small, less than 1,000 restorations per year	107,611	12
Larger, more than 1,000 restorations per year	251,937	12
Deprived area		
Low SES	106,370	3
Medium SES	213,039	18
High SES	40,139	3
Operators experience		
Graduated in or before 1980	162,690	27
Graduated between 1981 and 1990	138,125	17
Graduated in or after 1990	58,733	23
Patient's characteristics, N=75,556 patients		
Gender		
Male	175,151	
Female	184,397	
Age		
5-15 years	27,319	
16-25 years	66,281	
26-45 years	155,728	
46-65 years	96,141	
66 years and older	14,079	
Tooth and restoration characteristics N=359,548		
Tooth type		
Anterior	74,144	
Posterior	285,404	
Number of surfaces		
1	108,183	
2	145,543	
3	81,992	
≥4	23,830	

Table 2. Annual Failure Rates (over 10 years) and frequencies for practice related factors. Practices are ordered by increasing AFR

AFR	N	Follow up time	Size
2.3%	5,827	3.75 years	Group >3 dent.
2.6%	18,327	15 years	Group 2-3 dent.
2.7%	8,616	12 years	Group 2-3 dent.
3.4%	14,802	12 years	Group 2-3 dent.
3.5%	16,172	12 years	Group 2-3 dent.
3.7%	10,830	15 years	Solo
3.8%	4,761	12 years	Solo
3.9%	13,016	12 years	Group 2-3 dent.
4.1%	6,642	15 years	Solo
4.4%	16,043	12 years	Group >3 dent.
4.8%	3,643	12 years	Group >3 dent.
5.1%	18,798	12 years	Group 2-3 dent.
5.2%	7,050	12 years	Group 2-3 dent.
5.3%	10,891	12 years	Solo
5.4%	18,190	15 years	Group 2-3 dent.
5.6%	24,392	15 years	Group 2-3 dent.
5.7%	67,886	12 years	Group >3 dent.
5.7%	8,008	12 years	Solo
5.7%	16,872	15 years	Solo
5.8%	11,958	12 years	Group 2-3 dent.
5.9%	11,865	12 years	Group 2-3 dent.
6.0%	12,138	15 years	Solo
7.4%	21,612	15 years	Group 2-3 dent.
7.9%	11,209	15 years	Solo

Patient related factors

Table 4 shows the variation in AFR according to age group, gender and the presence of a removable denture. The number of included restorations in the gender subgroups was corrected for multiple restorations per patient and shows the number of male and female patients included in the study. The AFR was highest in the oldest age group compared to the younger age groups (6.9% vs. 4.2–5.0%). The AFR did not show a clear difference according to gender. Restorations in patients without any removable denture showed a better survival compared to restorations in both groups with a removable denture.

Table 3. Annual Failure Rates (over 10 years) and number of included restorations in practice/ operator related subgroups.

Location	N	AFR
Urban	211,605	4.8%
Rural	147,943	4.4%
Type of practice	**N**	**AFR**
Solo	81,351	4.6%
Small group with 2 or 3 dentists	184,798	4.4%
Larger group 4 or more dentists	93,399	5.5%
Practice size	**N**	**AFR**
Small, less than 1,000 restorations per year	107,611	4.7%
Larger, more than 1,000 restorations per year	251,937	4,7%
Deprived area	**N**	**AFR**
Low SES	106,370	5.6%
Medium SES	213,039	4.2%
High SES	40,139	5.0%
Operators experience	**N**	**AFR**
≤ 1980	162,690	4.7%
1981 – 1990	138,125	4.6%
≥ 1990	58,733	5.0%

Table 4. Annual Failure Rates (over 10 years) and number of included restorations (or patients for factor gender) for patient factor related subgroups.

Age group	N	AFR
5 – 15 years	27,319	5.0%
16 – 25 years	66,281	4.2%
26 – 45 years	155,728	4.5%
46 – 65 years	96,141	5.0%
66 – 95 years	14,079	6.9%
Gender	**N (patients)**	**AFR**
Male	39,205	4.8%
Female	36,351	4.5%
Presence of a removable denture	**N**	**AFR**
No removable denture	334,984	4.5%
Removable partial denture in either jaw	17,965	6.7%
Full denture in opposite jaw	6,599	8.4%

Tooth/restoration related factors

Results for the tooth/restorations related factors can be found in table 5. Out of 359,548 restorations, most were placed in molars followed by premolars and anterior teeth. Restorations in molars showed a lower survival (AFR 5.2%) than those in anterior teeth (AFR 4.4%) and premolars (AFR 4.0). The first molar was the most restored tooth and also showed the highest AFR. More restorations were placed in the upper jaw, but comparing the four quadrants, the AFR of restorations is similar. Most restorations were one and two surface restorations, and the AFR increased with increasing surface involvement from 4.3% for 1-surface restorations to 6.0% for ≥4-surface restorations. The most striking factor involved endodontic treatment, where the AFR was 11.0%, while the AFR in vital teeth was 4.7%. These results are illustrated in Figure 1, visualizing the fact that after 10 years, less than 20% of restorations in endodontically treated teeth had survived.

By far the most common restorative material used by the participating GDPs was composite. The overall 10-year AFR of composite restorations was 4.4%, compared to 5.1% for amalgam, 7.5% for compomer and 11.1% for glass ionomer cement restorations.

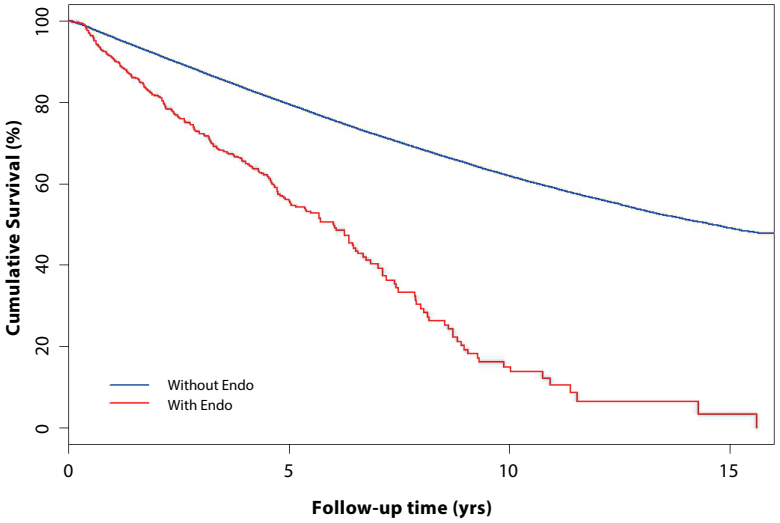

Figure 1. Survival graph of restorations in teeth with and without endodontic treatment.

Table 5. Annual Failure Rates (over 10 years) and number of restorations for tooth/restoration factor related subgroups.

Tooth	N	AFR
1	26,853	4.8%
2	22,056	4.2%
3	25,235	4.2%
4	46,041	3.6%
5	62,348	4.3%
6	93,063	5.7%
7	75,579	4.8%
8	8,373	4.2%
Tooth Group	**N**	**AFR**
Anterior	74,144	4.4%
Premolar	108,389	4.0%
Molar	177,015	5.2%
Jaw	**N**	**AFR**
Upper	202,668	4.7%
Lower	156,880	4.6%
Quadrant	**N**	**AFR**
1st	99871	4.6%
2nd	102,797	4.7%
3rd	79,135	4.7%
4th	77,745	4.6%
Surfaces	**N**	**AFR**
1	108,183	4.3%
2	145,543	4.4%
3	81,992	5.2%
≥ 4	23,830	6.0%
Endodontic treatment	**N**	**AFR**
Yes	860	11.0%
No	358,688	4.7%
Restorative material anterior	**N**	**AFR**
Composite	70,869	4.4%
Amalgam	2,567	4.0%
Compomer	162	6.0%
Glass Ionomer cement	546	10.1%
Restorative material posterior	**N**	**AFR**
Composite	240,701	4.4%
Amalgam	34,510	5.2%
Compomer	1,616	7.6%
Glass Ionomer cement	8,577	11.2%

Discussion

As far as we are aware, this is the first practice based study reporting on a dataset of more than 350.000 restorations. To date, the largest longitudinal study based on restorations placed by GDPs is the set of papers based on the insurance data from the English NHS public health system [5, 15, 16, 24]. In those studies, the re-intervention observation was based on a new payment related to a restoration in the same tooth in the same patient. This indirect method for following restorations has the disadvantage that it is not known whether additional restoration replacements were paid privately, or if patients have changed their insurance modality. For the present dataset from 24 practices, patients were regular attendees of the practice who only very rarely visited other dentists for treatment: usually for emergency treatment. If patients were referred to a specialized dentist or oral surgeon, these treatments are not in the dataset. However, in the Netherlands, only a limited number of treatments are referred to an oral surgeon such as complicated extractions and apical surgery. Referrals to specialized dentists are almost entirely limited to complicated endodontic cases and extensive periodontal treatments, neither of which are expected to influence restoration survival greatly. Therefore, the date of the last check up was the last moment that restorations were inspected on their clinical acceptability by the GDP and as a result, this date was used as censoring date for the survival analyses. This results in a nearly complete collection of all treatments that a patient received during the observation period.

The most important limitation of the present dataset is that the indication of treatment, the diagnosis resulting in the treatment decision, is missing. It is unknown why dentists decided to repair or replace a restoration. Dentistry in the Netherlands is remunerated with a fixed fee per item, each item indicated with a unique code. Data collection in this study was performed by downloading the occurrence of these codes as related to individual teeth. Information about treatment indication and diagnostic details are mostly entered in text fields in the programs. It was not feasible to retrieve and analyse text fields from the EPF with the present number of included restorations. In the future, the quality of the EPF will be improved by putting diagnoses in drop-down menus whereby the GDPs are forced to record the diagnosis, enabling secondary data analysis for those aspects.

As the dataset is large and inhomogeneous, it was considered as not appropriate to do a multi variable analysis. Therefore, we decided to present the general outcome of the entire dataset to provide a first impression on the restorative practice of GDPs. We also have not performed statistical tests on the Kaplan Meier graphs (e.g., Log-rank test) as this would be clearly inappropriate too considering the multi variable dataset. In subsequent

papers we will discuss the outcome for posterior and anterior restorations separately and will perform multi variable statistical analyses in addition to the Kaplan-Meier statistics for the subgroups. Moreover, as a multi variable analysis on a specific selection of the dataset, e.g. class II restorations, will be based on a different and more homogenous dataset, this might result in confusing contradictions with a possible outcome of a multi variable analysis of the overall dataset.

The results were explored on different levels: practice/dentist, patient and tooth/restoration level. Considerable variation in longevity of restorations between the practices was found, with the AFR showing values between 2.3% and 7.9%. Translated into median survival values this would be a range from 6 to 21 years. Previous longevity studies in general practices [8, 20, 26] on direct restorations are showing an even wider variation in AFR: between 1 and 15%. However, considering that all dentists joined the network because they were interested in having their restorative work evaluated, as well as improving their quality of work by receiving feedback from colleagues on their results, we still consider the observed variation to be large.

The accuracy and skills of the practitioners may differ, but also the threshold for repairing or replacing a restoration may vary widely. The decision for replacing a restoration is based on the clinical expertise of the practitioner during check-up, rather than on strict criteria such as USPHS criteria [27] and it has been shown previously that dentists may make very different decisions when cases of defective restorations are presented to them [28]. This can be seen as operator confounding, and as such is hard to avoid in true practice based research, but as it clearly reflects the real clinical situation it should be included as a factor of interest. We hypothesize that studies on clinical decision making by dentists may result in different ''dentist profiles'' as being proactive: more eager to replace in an attempt to prevent complications, or reactive: postponing interventions until a complication occurs and patients ask for help. Such profiles may be useful to investigate the influence of decision making on restoration survival.

Our results seem to point towards a lower restorations survival for larger team practices. Multi variable analysis must show whether this effect is still present when compensating for other factors, such as the experience of the dentist. However, one explanation may be that, in large practices, patients are more often seen by different dentists. It has been shown that changing dentists leads to a higher replacement rate of fillings [26].

In accordance with other studies, differences in AFR were found between patient age groups: restorations placed in the elderly showing a higher AFR compared to the other age categories [15]. Also, patients with a full or partial removable denture had a considerably lower survival of restorations compared to patients without such prostheses. This may reflect the overall state of the oral health of a patient with those having a denture probably experiencing more caries and periodontal problems resulting in more failed restorations and extractions.

In accordance with other practices based studies [5, 20]; we found a lower AFR for restorations in premolar and anterior teeth compared to molar teeth, and the presence of an endodontic treatment and more extended restorations as possible additional risk factors for re-intervention. However, out of the 359,548 restorations, only 860 were placed in endodontically treated teeth. It is likely that the number of endodontically treated teeth is higher, especially as root canal treatments from the period previously to the observation period will be not recorded in the dataset. However, a clear and significant effect is already found and it is likely that the HR will be increased when more endodontically treated teeth would be identified as such. In this study, posterior composite restorations showed the tendency for better performance. Only one previous paper [8] reported a better survival for composite restorations compared to amalgam restoration in low caries risk patients. The higher annual failure rate of glass ionomer restorations is in accordance with other clinical studies [29] but this result is probably highly biased by the fact the material is mostly used for temporary restorations such as closing the access opening after endodontic treatments and for emergency repairs.

It can be concluded that the investigated GDPs place restorations with a satisfactory longevity (mean AFR 4.6% over 10 years) but that substantial differences in outcome between practitioners exist. Several potential risk factors on practice/operator, patient, and tooth/restoration level have been identified and require further investigation.

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Chapter 3

10 year survival of Class II restorations placed by general practitioners

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Abstract

The aim of this retrospective practice-based study was to investigate the survival of direct class II restorations placed by a group of general dental practitioners (GDPs) and to analyze the effect of practice, patient, and tooth/restoration related factors. Electronic Patient Files of 24 general dental practices were used for collecting the data for this study. From the patient files, survival rates of 222,836 composite, amalgam, glass-ionomer and compomer placed in 61,121 patients by 67 GDPs between 1999 and 2011 were analyzed by Kaplan-Meier statistics and a multiple Cox regression. The investigated group of GDPs place restorations with a satisfactory survival (mean AFR_{10} 4.9% (95% CI 2.1 – 7.7), although a wide variation in annual failure rate (AFR) exists between the different operators varying between 2.6% and 7.0%. Restorations placed in young adults (21-30 years old) survived longest, whereas they showed a shorter survival in children (HR 1.553) and elderly (HR 1.593). Restorations in molar teeth, restorations placed in endodontically treated teeth and multi-surface restorations are more at risk for re-intervention. However, restoration size (included surfaces) has greater impact on restoration survival in premolar teeth. For the future, improved data collection on practice/operator, patient and tooth/restoration level, for example risk assessment and diagnoses, will provide the opportunity to evaluate even more extensively the risk factors involved.

Introduction

Placing and replacing of direct restorations is core business of general dental practitioners (GDPs). For Class II restorations in posterior teeth, a shift has taken place from amalgam towards composite resin as the material of choice [1, 2]. Systematic reviews show that posterior class II restorations have a good survival with Annual Failure Rates (AFRs) varying between 1 and 4% [3-8]. However, the clinical studies on which these reviews are based, are mostly prospectively designed trials performed in university settings. While these studies, keeping variables under control, show the potential performance of restorations under ideal conditions [6], in practice based studies risk factors on different levels are present and can be investigated [8, 9]. Only few data of selected general practices is available [9-14] as well as data from Scandinavian public health care [14, 15] showing AFRs varying from those comparable to university studies of 1-2% up to higher failure rates (4-5%) especially for high caries risk groups [9, 10]. Survival data on posterior restorations placed by larger groups of GDPs often results from cross-sectional studies, suggesting limited survival of posterior amalgam and especially composite restorations with median survival times of 5 to 8 years [16-18]. However, the cross-sectional study design has been proven to result in a gross underestimation of real survival times [19]. Higher failure rates compared to university based studies of 5% are also reported in studies based on NHS insurance databases [20-23], but for posterior class II restorations these data are limited to amalgam as composite was not allowed at the time.

Nowadays, electronic Patient Files (EPFs) are used by many dentists and the EPF might provide information on placement, replacement and censoring date of all restorations placed by the GDP, information required to make a reliable survival analysis. In practice based studies, all kind of high risk patients may be involved, considerable indication bias may be present and restorative procedures are not well controlled, but this is inevitable when real world dentistry is to be investigated.

A previous paper from our group [24] reported retrospectively on a practice base study, using data from EPFs of a set of more than 350.000 restorations, and addressed several influencing factors on restorations survival. Moreover, when comparing several dentists and practices, risk factors may be present at the practice / operator level, the patient level as well as the level of the tooth/restoration.

At practice / operator level the factors age, gender, and experience level have been investigated, but also the effect of patients changing their dentist has been demonstrated as a relevant risk factor [23]. Although results are scarce, the operator may be assumed to play a major role in restoration performance [4, 25].

Risk factors that have been identified on patient level are gender, age and individual characteristics such as caries risk or bruxism [8, 9, 21]. Also, socio-economic status has been reported as being associated with risk of failure [26].

At the tooth / restoration level tooth type, size of the restoration as well as the type of restorative material used may play a role. A higher survival for restorations in premolars compared to molars has been reported [22, 27], but not confirmed by others [28]. Several studies showed a lower survival for larger restorations [12, 22, 24, 29], but again this was not always confirmed [9, 27, 28].

While the previous report [24] included both anterior and posterior restorations and the inhomogeneous dataset precluded a multi variable analysis, the present study aims to investigate the survival of the subset of direct class II restorations from that study and to analyze risk factors on practice, patient and tooth/restoration levels.

Materials and Methods

Inclusion and data collection

Data from class II posterior restorations placed in permanent teeth, as recorded by the electronic patient files of general dental practices that joined a practice based research group were the basis of this retrospective study. These practices volunteered to have their restorative work evaluated on restoration survival and wanted to improve their quality of work. Only practitioners that contributed a minimum of 200 restorations were included (n=222,836). Also, only restorations were included from those patients that visited the practice for regular check-ups. Data on direct class II restorations placed between 1999 and 2011 were digitally extracted from the EPF, transformed into an Excel data file and sent to the research group using an application designed by two involved software firms (Exquise®, Kwadijk, NL; Complan®, Heerhugowaard, NL). Patient data were coded and only the practitioners held the code list for their own patients. Design and protocol were approved by the local ethics committee, METC (CMO Arnhem-Nijmegen file nr. 2013/483). The research data are securely stored on the server of Radboud University Medical Centre and can be accessed by all the authors.

Outcome parameters

Dates of class II restoration placement, last check-up visit of the patient and dates of re-intervention were recorded. When no intervention was performed on a restoration, the restoration was considered successful and censored at the date of the last check up. The restoration was considered failed if it was replaced or repaired, the tooth was extracted, or in case of a prosthetic or endodontic treatment. When a new restoration was placed in the same tooth and one or more surfaces of the previous restoration were involved, this was defined as an intervention on the restoration and thus was considered a failure. An exception was made for mesial-occlusal (MO) and distal-occlusal (DO) class II restorations. When a MO restoration was placed as the first restoration and the intervention treatment was a DO restoration, analysis for the initial restoration was censored. Many MO and DO restorations in posterior teeth are two independent (box type) restorations, and it would not be appropriate to qualify placement of the second restoration as a failure of the first one.

Independent variables

At the practice/operator level, the number of operators in the practice was recorded. Three types of practices were defined: solo, small (2 or 3 dentists) or larger group practices (≥4 dentists).

At the patient level, gender, age and the presence of a removable denture were recorded. Regarding age, patients were divided into 6 groups; 5-12 years (children), 13-20 years (adolescents), 21-30 years (young adults), 31-50 years (adults), 51-70 years (older adults) and 70-95 years (elderly). Removable denture presence was grouped into three categories: no denture present, partial denture present in same or opposing jaw, and full denture present in opposing jaw.

At the tooth level; tooth number (FDI system), number of restored surfaces, existing endodontic treatment (yes/no) and applied restorative material type (amalgam, composite, glass-ionomer and compomer) were recorded. Bases on the tooth number, teeth were divided into premolars or molars and by jaw.

Statistical analysis

Statistical analyses were performed with SPSS 22 and R 3.2.2. Restoration survival was explored with survival tables and Kaplan Meier graphs. Out of the survival tables, mean Annual Failure Rate over 10 years (AFR_{10}) was calculated according to the formula: $AFR_{10}(\%) = 1 - \sqrt[10]{x} * 100$, in which 'x' level of survival.

A multiple Cox regression analysis with clustering data for patients with multiple restorations was conducted with restoration failure as dependent variable and as independent variables: practice/operators characteristics (type of practice, operator itself), patient characteristics (gender, age, presence of a removable denture) and tooth/restoration characteristics (tooth type, arch, number of restored surfaces, endodontic treatment and used restorative material). As most patients and all practices/operators in the study contributed with multiple restorations, the method described by Chuang et al., to produce statistically valid standard errors for the estimates of survival, was performed [30]. An interaction was found between effect of the variable premolars/molars and number of surfaces. Therefore the multiple Cox regression model was extended to calculate the effect of restoration extension for premolars and molars separately. When applying multiple Cox regression models, the hazard ratios are all estimated as adjusted effect. That is the effect of a specific single independent variable, while disconnecting it from all other independent variables in the model. Therefore the adjusted hazard ratios give the best estimate of the effect of independent variables. As the adjusted multi variable regression is considered the highest standard of survival analysis, all analytical results reported will relate to the adjusted analysis.

Results

Restorations placed by 67 GDPs working in 24 practices were included in the dataset. 222,836 class II restorations were placed in 61,121 patients (29,472 male; 31,649 female; age 5 - 95 years; mean age 37.9 years 95% CI 10.5 – 65.2). The mean number of included restorations per patient was 3.6 and ranged between 1 and 17 restorations. The observation period varied between 3.75 and 12 years (mean observation time 11.6 years 95% CI 8.3 – 15.0). The mean calculated AFR_{10} was 4.9% (95% CI 2.1 – 7.7) and ranged within operators between 2.6% and 7.0%. The collected data from these patients was considered homogeneous and suitable for multi variable regression analysis. Table 1 shows the results of the Kaplan Meier and adjusted multi variable regression analysis.

Practice/operator related factors

Practice type was identified as a risk factor, with restorations placed in solo practices showing a higher AFR_{10} and risk for failure compared to small group practices (HR 0.689), and a longer survival compared to large group practices (HR 1.221). Figure 1 shows the Kaplan Meier survival of the 24 different general dental practices. The AFR_{10} for restorations made within the practice with the highest survival was 2.6%, while it was 7,0% in the practice with the lowest survival.

Table 1. Frequencies, annual failure rates (after 10 years), P-values and Hazard ratios for practice, patient, tooth and restorations related factors.

	N restorations	AFR	P-value	HR (95% CI)
Practice characteristics, N=24 practices				
Type of practice				
Solo	48.938	4.7%	-	1.00
Small group, 2-3 dentists	113.054	4.6%	<.001	0.689 (0.600 - 0.792)
Larger group, more than 3 dentists	60.844	6.2%	<.001	1.221 (1.120 - 1.332)
Patient characteristics, N= 60 245 patients				
Gender				
Male	114.044	5.2%	-	1.00
Female	108.792	4.7%	<.001	0.953 (0.932 - 0.974)
Age group				
5-12 years	3.855	7.3%	<.001	1.553 (1.447 - 1.667)
13-20 years	26.736	5.2%	<.001	1.164 (1.117 - 1.214)
21-30 years	41.617	4.5%	-	1.00
31-50 years	112.533	4.8%	<.001	1.073 (1.041 - 1.105)
51-70 years	35.177	5.4%	<.001	1.215 (1.169 - 1.263)
71 – 96 years	2.918	7.7%	<.001	1.593 (1.450 - 1.750)
Presence of a removable denture				
Full denture	2.690	8.0%	-	1.00
Partial denture	8.063	6.5%	<.001	0.812 (0.739 - 0.892)
No removable denture	212.083	4.8%	<.001	0.553 (0.508 - 0.601)
Tooth and restoration characteristics N=222 836				
Tooth type				
Premolar	92.978	4.0%	-	1.00
Molar	129.858	5.7%	<.001	2.329 (2.154 – 2.519)
Arch				
Lower jaw	101.245	5.0%	-	1.00
Upper jaw	121.591	4.8%	0.918	1.001 (0.983 – 1.012)
Number of surfaces premolar				
2	55.744	3.5%	-	1.00
3	32.051	4.5%	<.001	1.360 (1.321 – 1.401)
≥4	5.183	5.8%	<.001	1.518 (1.474 - 1.563)
Number of surfaces molar				
2	71.670	5.5%	-	1.00
3	42.586	5.8%	<.001	1.116 (1.097 – 1.135)
≥4	15.602	6.0%	<.001	1.245 (1.223 – 1.267)
Endodontic treatment				
No	222.259	4.9%	-	1.00
Yes	577	13.4%	<.001	2.251 (1.962 – 2.581)

Table 1. Continued

Used restorative material				
Composite	188.683	4.6%	-	1.00
Amalgam	27.893	5.2%	<.001	1.144 (1.107 – 1.183)
Glass Ionomer	5.569	13.9%	<.001	2.982 (2.846 – 3.124)
Compomer	691	13.2%	<.001	2.351 (2.072 - 2.668)

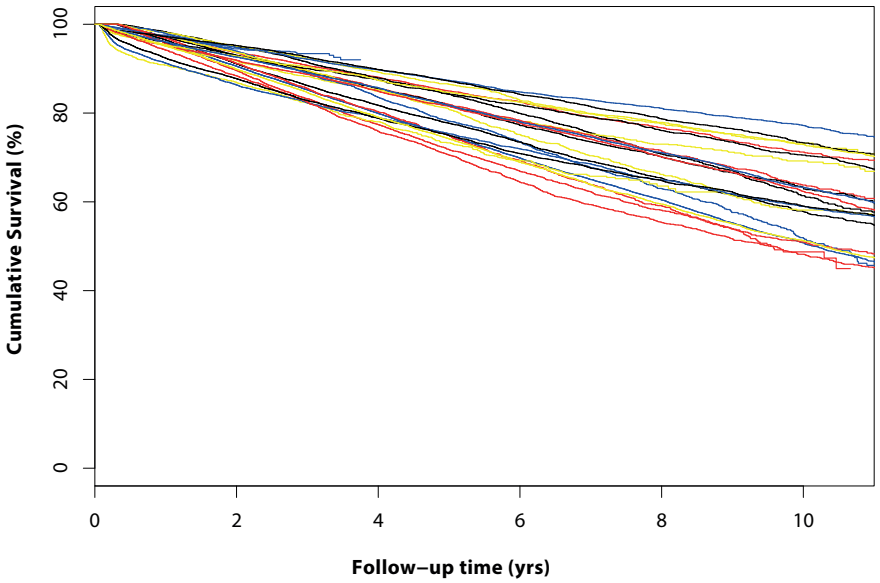

Figure 1. Survival graph of restorations in the 24 general dental practices.

Patient related factors

All investigated patient characteristics were shown to play a statistically significant role in the survival of the restorations. Restorations in male patients showed a shorter survival compared to restorations in female patients (HR 0.953). Restorations placed in young adults (21-30 years old) survived longest, whereas they showed shorter survival especially in children (HR 1.553) and the elderly (HR 1.593). These results are illustrated in the Kaplan Meier graph in figure 2. The presence of a partial or full removable denture compromised restoration survival.

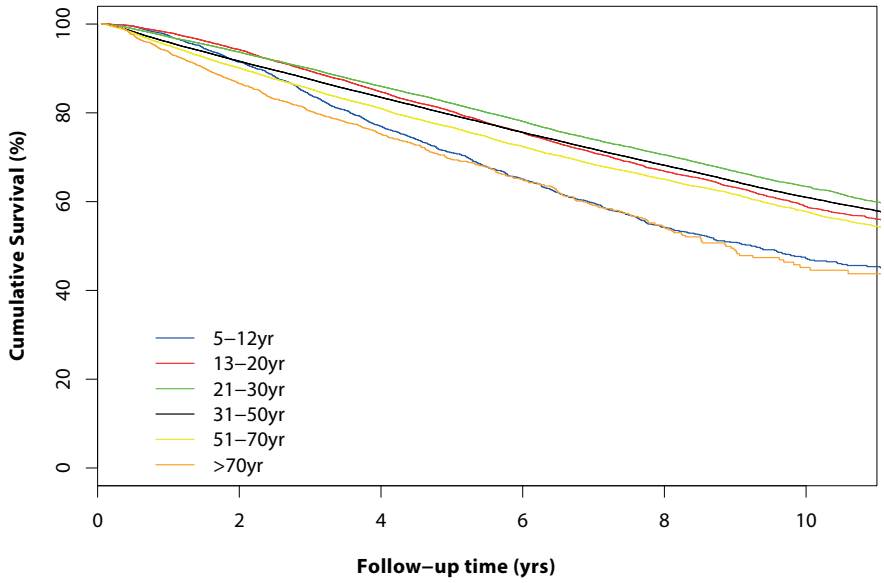

Figure 2. Survival graph of restorations divided by age group.

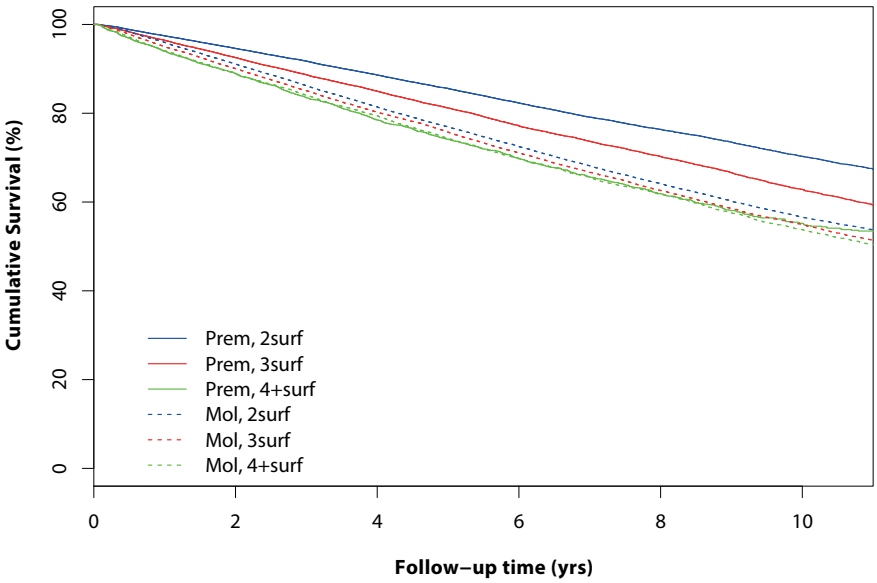

Figure 3. Survival graph of 2-,3-, ≥ 4 surface restorations in premolar and molar teeth.

Tooth/restoration related factors

Restorations in premolars showed better survival than those in molars (HR 2.329). Most restorations were two surface restorations, and the AFR_{10} and HR increased with higher surface involvement. Figure 3 shows the Kaplan Meier survival of 2, 3 and ≥4 surface restorations in premolar and molar teeth. Longest survival was seen in 2-surface restorations in premolar teeth (AFR_{10} of 3.5%). Moreover, from the graph it seems that the number of surfaces of molar restorations does not seem to influence the survival as much as in premolar teeth, which is confirmed by the results from the Cox regression. Another factor of main importance is the presence of an endodontic treatment. Where the AFR_{10} for vital teeth was 4.9%, the HR of a restoration in an endodontically treated tooth was 2.251 and the AFR_{10} was calculated as 13.4% . Differences between materials were also found, with composite restorations showing the lowest AFR_{10} and HR.

Discussion

This large, long-term practice based study evaluated the clinical performance of class II restorations placed under the full spectrum of risk conditions and identified variables that influence the quality of everyday restorative care. The largest practice based longevity studies based on Kaplan-Meier statistics included more than 500.000 restorations, but combined posterior and anterior restorations and was based on insurance data [20-23]. The present dataset has a higher degree of reliability for survival analysis as data were retrieved from EPFs and the included patients were loyal to the practice including regular check-ups. Therefore, inaccuracies will be limited to administrative mistakes in data reporting, and missing data due to referred treatments or our-of-hours emergency treatments outside the practice.

The practices were distributed over the country and patients from different social classes were included. The practice / operator group cannot be considered as representative for the Dutch situation as they volunteered to participate in research. As such, at best it provides a good impression what takes place in a group of motivated GDPs, offering routine daily care. Similar studies, with at least 5 years observation time have either been limited to single practices including one or two practitioners [10-12], or have been based on public health care data [14, 15, 31].

An important objective of the present study was to identify risk factors influencing restoration survival. It was not possible to investigate all important risk factors like caries risk, bruxism, general health, periodontal status as such information was not commonly available in the EPF. Also the diagnosis underlying restoration placement or intervention was absent. There is a clear need for EPF software improvement, to help dentists to record such vitally important data for research and quality assessment.

There are two main findings from the present study that especially should be mentioned. Firstly, a mean AFR of 4.9% (95% CI 2.1–7.7) was found for the included practices, translated into a median survival time of 10-12 years, which is much better than survival data presented by cross sectional studies in the past [16-18]. Therefore, the present study confirms the findings that such cross-sectional studies result in a gross underestimation of survival [19] and to our knowledge is the first study to report reliably on the survival of posterior restorations placed by a large group of general practitoners . A wide range of survival is also found in other long term studies with at least 5 year follow up, varying from 1.1% to 8.6% [15, 28, 32-35] and the results of this study are within this range.

The second important finding is that differences in AFR between individual GDPs were considerable with a range of 2,5 to 7%, especially considering the fact that these operators had an above average focus on quality control. Therefore, it seems that the dentist is playing an important factor in restoration survival. The observed differences may be related to operator skills, but it is perhaps even more likely that they are also related to practice organization, different patient needs and demands and intervention choices by the dentists. Differences in treatment decisions between practitioners were shown to be considerable [36], and dentists may perhaps be characterised by a preference for early intervention to prevent more serious failures (pro-active) or on the other hand for late intervention to prevent unnecessary treatment (reactive), which may be closely related to variation in survival times. However, this is highly speculative and more research is needed to investigate the influence of decision making on restoration survival.

Practice type was found to be a significant factor in restoration survival, larger group practices showing an increase of risk of failure compared to solo practices. Working in a group practice might result in check-ups being performed by another dentist, which might result in a higher risk for intervention as changing dentists was found to be a risk factor [23, 37]. However, interpretation of practice and dentist influence should be done with great care as the number of practices and operators is limited and unknown factors on practice level may play a role.

At the patient level, some ''high risk groups" can be identified in the present study. Children (5-12 yrs) and elderly (71-96 yrs), respectively, showed a 58.8% and 68.2% higher risk for re-intervention as compared to the young adult group. In young children, primary or secondary caries is the almost exclusive reason for restoration (re)placement [38, 39]. Therefore, the youngest group in our study was likely to have a high caries risk and this would result in a lower restoration survival [8, 9]. Elderly people are more often medically compromised, maintaining a good oral hygiene may be more difficult and this may also increase caries risk. Moreover, this generation often has a compromised dentition with missing teeth and large restorations already present. The risk factor "presence of a removable prosthetic appliance", which was shown have a relatively strong effect, may also be a reflection of these compromised dentitions.

At the tooth/restoration level, this study showed that small restorations in vital premolar teeth are performing best, which is in accordance with other studies [12, 22, 40]. The number of surfaces influenced restoration survival in premolar teeth more than in molar teeth, however, overall a much better survival for restorations in premolars was found. The presence of an endodontic treatment in the tooth was found to be a major risk factor. However, from the 222,836 class II restorations, only 597 were recorded to be placed in endodontically treated teeth, while it is likely that the number of endodontically treated teeth is higher. As root canal treatments from the period previous to the observation period were not recorded in the dataset, a considerable under-identification must be assumed.

Posterior composite restorations showed the longest restoration survival in this study, even higher than amalgam restorations, a result reported only once for low caries risk patients [10]. However, the effect of indication bias should be considered in this respect. Patient demand for replacing amalgam restorations for aesthetic reasons may have reduced survival, and also dentists may have chosen amalgam over composite in specific situations, for instance with problematic moisture control or for patients / locations with poor oral hygiene. However, even assuming equal performance of these materials in this study is noteworthy, as a recent Cochrane review still confirmed the superiority of amalgam [41]. In accordance with other clinical studies [7], glass-ionomer and compomer restorations showed a shorter survival compared to composite and amalgam restorations. Again, indication bias must be assumed as many glass-ionomer restorations will be temporarily placed, for instance in deep caries cases or after a root canal treatment. Moreover, these materials are likely to be used more in high risk patients and locations.

Within the limitations of our study, the results suggest that, compared to what is found in university based trials, restoration survival in general dental practice in the Netherlands are lower with AFR_{10} of 4.9% (95% CI 2.1 – 7.7). Differences between dentists are considerable and may to some degree be explained by different patient groups and routine care factors. For the future, improved data collection on practice/operator, patient and tooth/restoration level, for example risk assessment and diagnoses, will provide the opportunity to evaluate even more extensively the risk factors involved.

Conclusions

- The investigated GDPs place restorations with a satisfactory survival (mean AFR_{10} 4,9% (95% CI 2.1 – 7.7)
- A substantial variation in restoration AFR between practitioners exists.
- Age of the patient influences the survival of direct class II restorations. Restorations in children and elderly are more likely to fail.
- Restorations in molars are more susceptible to failure, but restoration size (included surfaces) has a greater impact on restoration survival in premolar teeth.
- Composite and amalgam restorations showed comparable survival.

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Chapter 4

Risk factors for dental restoration survival, a practice based study

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Abstract

To improve patient dental care, it is necessary to identify possible risk factors for failing of restorations. This practice-based cohort study investigated the performance and the influence of possible risk factors on practice, patient, tooth and restoration level on survival of direct class II restorations. Electronic patient files from 11 Dutch general practices were collected and 31,472 restorations placed between January 2015 and October 2017 were analyzed. Kaplan Meier statistics were performed, annual failure rates (AFRs) were calculated, and variables were assessed by multi-variable Cox regression analysis. The observation time of restorations varied from 0 to 2.7 years, resulting in a mean AFR of 7.8 % at 2 years. However, wide variation in AFRs exists between the different operators varying between 3.6% and 11.4%. A plethora of patient related variables such as age of the patient ($HR_{elderly}$: 1.372), general health ($_{HRmedically\ compromised}$: 1.478), periodontal status ($HR_{periodontal\ problems}$: 1.207), caries risk and risk for parafunctional habits (HR_{high}: 1.687), restorations in molar teeth (HR_{molar}: 1.383), restorations placed in endodontically treated teeth (HR_{endo}: 1.890) and multi-surface restorations are at a high risk for re-intervention ($HR_{\geq 4\ surfaces}$: 1.345). Restorations placed due to fracture were more prone to fail than restorations placed due to caries. Excluding patient related risk factors, remaining risk factors considerably changed in their effect and significance. The effect of operator, age of the patient and endodontic treatment increased, effect of the diagnosis decreased and the Socio-Economic-Status became significant (HR_{high}: 0.873). This study demonstrated that a wide variation of risk factors on practice, patient and tooth level influences the survival of class II restorations. To provide personalized dental care, it is important to identify and record potential risk factors. Therefore, the authors recommend further clinical studies to include these patients' risk factors in the data collection and the analysis.

Introduction

Knowledge about factors influencing survival of direct class II restorations can improve patient care. Most clinical studies published on dental restorations aimed to evaluate the performance of new materials and techniques often in a selected patient group in university clinics with under powering and too short observation times identified as possible problems [1]. Systematic reviews based on this type of studies resulted in excellent survival rates for composite restorations [2].

Furthermore, in the last decade, there is increasing support for acknowledging that materials and their properties are not the decisive factors in restoration survival [3]. Clinical retrospective and practice based studies have been published showing that patient related factors, such as caries risk and bruxism [4-6], patient's socio economic status [7,8] are variables of main importance in restoration survival. Systematic reviews including patient related risk factors show that their influence on restoration performance is not only significant, but also relevant, showing Hazard ratios from 2.5 up to 8.3 [9, 10].

Besides patient related factors, dentist factors like personal skills or treatment decisions [11-13] and health insurance policies [14] may play a significant role in survival of restorations placed in general practice as well.

To improve patient dental care, it is necessary to identify possible risk factors for failing of restorations. Therefore, we set up a study to investigate a large dataset of restorations, placed in a general practice environment and general population, but most importantly, included a wide range of possible variables on patient level. There have been reports published on these big data [11, 15, 16], however these studies are hampered by their retrospective nature and possible risk factors for restoration performance not included in the analysis, as General Dental Practitioners (GDP) did not include these factors in the patient files.

Growing tendency towards more personalized care in dentistry [17] and the public demand for transparency and shared decision making [18] drives the need for GDPs to extend the information in the electronic patient files (EPFs) as well as to identify risk factors on patient level. In the Netherlands, a country where almost all dental practices use EPFs and patients are loyal to their GDP, it was possible to analyse restoration performance for identification of possible risk factors for survival.

The aim of this study was to investigate the influence of possible risk factors on practice, patient, tooth and restoration level on longevity of direct class II restorations.

Materials and Methods

Inclusion and data collection

Data from EPFs of general practices joining a practice based research group were the basis of this cohort study. Data on direct class II restorations placed between 01-01-2015 and 01-10-2017 were digitally extracted, transformed into anonymized Excel files and sent to the researchers using an application designed by the involved software firm (Exquise®, Kwadijk, NL). Data validation has been performed by visiting all practices and checking 200 randomly selected patient files on data transition failures. Exclusion criteria were:

- Practitioners with less than 250 restorations.
- Patients not visiting for check-ups at least once a year
- Restorations with missing data on restorative materials or patients ZIP code.

Design and protocol were approved by the local ethics committee, METC (CMO Arnhem-Nijmegen file nr. 2015-1565).

Outcome parameters

Dates of class II restoration placement, last check-up visit of the patient and dates of re-intervention were recorded. When no intervention was performed on a restoration, it was considered successful and censored at the last check up date. When a new restoration was placed in the same tooth including one or more surfaces of the previous restoration, this was defined as an intervention on the restoration and considered a failure. Regardless of the diagnosis, extraction, endodontic or prosthetic treatments, were considered as failures. Exceptions were:

- Restorative interventions in the first month were ignored and initial restoration observation was censored.
- When a crown was placed within 1.5 year after initial direct restoration, this restoration likely served as base for a crown placement and was censored.
- When a MO restoration was placed as the first restoration and the intervention treatment was a DO restoration, analysis for the initial restoration was censored as many MO and DO restorations are likely independent (box type) restorations.

Independent variables

On practice level, the individual practitioner who placed the restoration was coded. On patient level, gender, age, socio-economic-status (SES), general health score, periodontal status, oral hygiene (based on the amount of plaque; poor/average/good), caries risk (low/high), presence of parafunctional habits (yes/no) and the presence of a removable denture (yes/no) were recorded. Patients were divided into 6 age groups. SES scores were provided by the Dutch Central Office for Statistics based on ZIP code, 3,546 areas were ranked and patients were categorized into low, medium and high SES. General health status was based on the American Society of Anaesthesiologists ASA-classification [19] dividing into healthy (score I), medically compromised (score 2) and severe medically compromised (score ≥3). Periodontal status was based on the Dutch Periodontal Screening Index (DPSI) (20) resulting in score A (bleeding on probing and/or calculus), B (pockets 4-5 mm without recession) and C (pockets 4-5 mm with recession or pockets ≥ 6 mm). High caries risk was scored based on the presence of active lesions, number of new caries lesions (1 or more new caries lesions in the last year) and frequent sugar consumption. Low risk was assigned for patients without active lesions and new caries lesions (last restoration due to caries 2 or more years ago) and sufficient plaque control [21]. Due lacking of guidelines and protocols, the assessment of parafunctional habit score was based on the question: "Is there non-physiological wear visible on teeth or restorations?" and considered indicators like exposed dentin, distinctive wear facets, fractures of restorations or teeth, hypertrophic chewing muscles.

On tooth level, tooth number, number of restored surfaces, existing endodontic treatment (yes/no), applied restorative material, adhesive system used and diagnosis for placing restorations were recorded. The dental practitioners were invited by the software to select the best matching diagnosis from a list:

- Caries on unrestored surface
- Caries on previously restored surface
- Fracture of the tooth or restoration
- Wear of the tooth or restoration
- Fracture prevention
- Restoration after endodontic treatment
- Aesthetic demands
- Orthodontic retainer
- Dislodged restoration
- Insufficient proximal contact
- Poor marginal adaptation
- Trauma
- Cracked tooth

GDPs were completely free to use restorative materials at their discretion. From 01-12-2015 until 01-02-2017 the Clearfil Majesty ES-2 (Kuraray Noritake, Osaka, JPN) hybrid resin composite and Clearfil SE Bond and Clearfil Protect bond (Kuraray Noritake, Osaka, JPN)

were provided to the practitioners for free. Regularly, treatments were carried out with the assistance of a dental nurse, only few practitioners used rubberdam isolation during restoration placement.

Statistical analysis

Statistical analyses were performed with SPSS 22 and R3.4.0. Longevity of restorations was explored with survival tables and Kaplan Meier graphs. Out of the survival tables, mean Annual Failure Rates over 2 years (AFR_2) were calculated according to the formula: AFR (%) = $1 - \sqrt[2]{x}$ * 100, in which 'x' level of survival after 2 years.

The use of routine data implies that data are missing, especially on those items that were relatively new to GDPs like specific risk indicators. Performing analyses on complete cases only, is likely to result in biased results [22]. As there is no indication that the chance of information being missing is depending on the missing data itself, we assumed that the MAR hypothesis is true. Under that assumption, we applied multiple imputation to deal with missing independent variables using a full conditional model with fiftyfold multiple imputation. Pooled results from the analyses on the fifty imputed datasets resulted in the data set for further statistical analysis. 61.1% of the restorations were lacking of an (partial) incomplete EPF, only present in the patient related variables; ASA score, DPSI, oral hygiene, caries risk and risk for parafunctional habits.

To explore impact of risk factors on restoration survival a multilevel Cox regression analysis, with clustering of data for patients with multiple restorations, was conducted. The method described by Chuang et al., to produce statistically valid standard errors for the estimates of survival, was performed [23]. In order to investigate the impact of patient related factors on direct restoration survival, the Cox regression was repeated with the exclusion of the individual patient characteristics from the analysis except the factor age. When the p-value of an independent variable in both Cox regressions met the significance level of <5%, the percentage difference between the two Hazard Ratio's was calculated by the formula: y=(x/z)–1)*100%, in which 'y' expresses the percentage difference, 'x' Hazard Ratio of the significant independent variable in the multiple Cox regression with patient factors excluded and 'z' Hazard Ratio of the significant independent variable in the multiple Cox regression with patient factors included.

To calculate the relation between diagnosis for placing a restoration and the patients risk profile, χ^2-tests were used ($p \leq 0.05$).

Results

Restorations placed by 22 GDPs in 11 practices (13 male, 9 female) were included; mean age 44.4 years (95%CI, 31.7-57.1), mean time since graduation 17.2 years (95%CI, 6.7-27.7). In advance restorations were excluded due to missing ZIP code (n=5), missing data on restorative material (7,697 restorations), no yearly follow up (378 patients) or being placed by practitioners performed less than 250 restorations (714 restorations). 31,472 class II restorations were included in the final dataset placed in 14,909 patients (7,377 male; 7,532 female; mean age 44.1years. The mean number of included restorations/ patient was 2.11 (95%CI, 1.34-2.88). The observation period varied between 0-33 months (mean observation time 9.2months). The collected data from these patients was considered homogeneous and suitable for multi-variable regression analysis.

Table 1. Diagnoses of the first performed interventions.

Diagnoses first intervention	No. interventions (%)	
Direct restoration		**2004 (67.8%)**
Caries	999 (33.8%)	
Fracture of tooth or restoration	531 (18.0%)	
Wear of tooth or restoration	176 (6.0%)	
Dislodged restoration	144 (4.9%)	
Insufficient contact point or margin	86 (2.9)	
Other (Aesthetics, orthodontic retainer, trauma, cracked tooth or fracture prevention)	68 (2.3%)	
Endodontic treatment	678 (23.0%)	**678 (23.0%)**
Crown		**75 (2.5%)**
Large direct restoration	36 (1.2%)	
Endodontically treated tooth	16 (0.5%)	
Crown replacement	13 (0.4%)	
Abutment tooth bridge or removable denture	10 (0.3%)	
Extraction		**199 (6.7%)**
Caries	37 (1.3%)	
Periodontitis	31 (1.0%)	
Periodontitis apicalis	62 (2.1%)	
(Vertical) Fracture (tooth or restoration)	54 (1.8%)	
Deviating position, orthodontic treatment, financial problems	15 (0.5%)	
Total	**2.956 (100%)**	**2.956 (100%)**

The mean calculated AFR_2 was 7.8% (95%CI, 7.6%-8.0%) and survival was 85.1% after 2 years. Table 1 shows the diagnoses for the intervention performed first. New direct restorations placement due to caries was the most common intervention, followed by an endodontic treatment.

Table 2 describes the results of the descriptive statistics, annual failure rates (after 2 year), the adjusted multi-variable regression analysis for the practice, patient, tooth and restoration related variables, as well as the regressions analysis with the exclusion of individual patient factors.

Practice/operator related factors

A wide variation in AFRs and HRs were found among practitioners and practices. AFR_2 among practitioners ranged from 3.6% to 11.7%. The practitioner effect on restorations survival strengthened when individual patients' factors were eliminated from the regression analysis.

Table 2. Descriptive statistics, annual failure rates (after 2 year), the adjusted multi-variable regression analysis for the practice, patient, tooth and restoration related variables and the repeated regressions analysis with the exclusion of individual patient factors and the percentage difference in Hazard Ratios.

	No. of restorations	Annual Failure Rate AFR (%)	P-value	Hazard Ratio$_1$ (95% Cnfidence interval) Patient factors included	P-value	Hazard Ratio$_2$ (95% Confidence interval) Patient factors excluded	Percentage difference in HR, with and without patient related factors included
Practice characteristics. N= 11 practices							
Practitioners (Practice_practitioner)							
1_1	2.251 (7.2%)	5.9	-	1.00	-	1.00	
2_1	1.887 6.0%)	8.2	<0.001*	1.813 (1.363 – 2.413)	<0.001*	1.970 (1.490 – 2.604)	8.64%
2_2	506 (1.6%)	5.9	0.358	1.282 (0.755 – 2.175)	0.241	1.372 (0.809 – 2.326)	
3_1	1.100 (3.5%)	5.6	0.124	0.759 (0.533 – 1.073)	0.932	0.985 (0.706 – 1.376)	
4_1	735 (2.3%)	11.6	0.007*	1.734 (1.163 – 2.586)	0.005*	1.773 (1.188 – 2.647)	2.25%
4_2	806 (2.6%)	7.5	0.039*	1.448 (1.018 – 2.059)	0.010*	1.573 (1.113 – 2.223)	8.67%
5_1	2.291 (7.3%)	5.7	0.376	1.156 (0.838 – 1.596)	0.062	1.344 (0.986 – 1.832)	
5_2	1.777 (5.6%)	5.9	0.983	1.004 (0.705 – 1.428)	0.325	1.189 (0.842 – 1.678)	
6_1	4.490 (14.3%)	10.7	0.004*	1.445 (1.123 – 1.858)	<0.001*	1.520 (1.182 – 1.953)	5.19%
6_2	470 (1.5%)	Incalculable	0.008*	1.908 (1.182 – 3.081)	0.002*	2.098 (1.301 – 3.381)	9.92%
6_3	2.006 (6.4%)	9.9	<0.001*	2.227 (1.664 – 2.981)	<0.001*	2.405 (1.804 – 3.206)	7.97%
7_1	877 (2.8%)	11.7	0.004*	1.727 (1.186 – 2.514)	0.003*	1.754 (1.217 – 2.527)	1.56%
7_2	1.347 (4.3%)	10.8	<0.001*	2.205 (1.627 – 2.989)	<0.001*	2.221 (1.644 – 3.000)	0.72%
8_1	657 (2.1%)	8.6	0.463	1.162 (0.778 – 1.733)	0.571	1.119 (0.758 – 1.653)	
8_2	303 (1.0%)	Incalculable	0.009*	2.884 (1.309 – 6.354)	0.002*	3.246 (1.522 – 6.920)	12.54%
9_1	1.252 (4.0%)	7.0	0.586	1.101 (0.778 – 1.558)	0.232	1.233 (0.875 – 1.738)	
10_1	3.621 (11.5%)	8.5	0.041*	1.373 (1.013 – 1.861)	0.035*	1.384 (1.023 – 1.872)	0.84%
11_1	1.475 (4.7%)	3.6	0.091	0.698 (0.461 – 1.059)	0.124	0.723 (0.478 – 1.093)	
11_2	1.151 (3.7%)	7.3	0.131	1.363 (0.912 – 2.037)	0.087*	1.412 (0.951 – 2.098)	
11_3	339 (1.1%)	Incalculable	<0.001*	4.722 (2.557 – 8.720)	<0.001*	5.061 (2.769 – 9.251)	7.16%
11_4	1.299 (4.1%)	4.1	0.729	0.932 (0.624 – 1.391)	0.966	0.991 (0.668 – 1.472)	
11_5	832 (2.6%)	7.9	0.277	1.222 (0.851 – 1.756)	0.092	1.358 (0.951 – 1.939)	

Table 2. Continued

	No. of restorations	Annual Failure Rate AFR (%)	P-value	Hazard Ratio$_1$ (95% Cnfidence interval) Patient factors included	P-value	Hazard Ratio$_2$ (95% Confidence interval) Patient factors excluded	Percentage difference in HR, with and without patient related factors included
Patient characteristics. N= 14.909 patients							
Gender							
Male	16.090 (51.1%)	8.4	-	-	-	1.00	
Female	15.382 (48.9%)	7.1	0.171	0.932 (0.842 – 1.031)	0.064	0.910 (0.824 – 1.005)	
Age group							
5-12 years	610 (1.9%)	6.1	-	1.00	-	1.00	
13-20 years	3.589 (11.4%)	8.1	0.069	1.236 (0.984 – 1.552)	0.020*	1.312 (1.044 – 1.650)	
21-30 years	4.681 (14.9%)	8.5	0.201	1.165 (0.922 – 1.474)	0.066	1.245 (0.986 – 1.573)	
31-50 years	12.390 (39.4%)	9.2	0.017*	1.314 (1.051 – 1.644)	0.002*	1.420 (1.141 – 1.767)	8.04%
51-70 years	8.883 (28.2%)	12.5	0.043*	1.247 (0.980 – 1.587)	0.002*	1.447 (1.151 – 1.820)	16.06%
71-96 years	1.319 (4.2%)	14.4	0.019*	1.372 (1.054 – 1.786)	<0.001*	1.800 (1.418 – 2.286)	31.21%
SES							
Low	10.211 (32.4%)	8.6	-	1.00	-	1.00	
Medium	7.632 (24.3%)	7.4	0.368	0.934 (0.806 – 1.083)	0.247	0.917 (0.792 – 1.062)	
High	13.629 (43.3%)	7.5	0.106	0.902 (0.796 – 1.022)	0.033*	0.873 (0.770 – 0.989)	
General health condition (ASA)							
Healthy	16.273 (51.7%)	7.1	-	1.00			
Medically compromised	5.641 (17.9%)	10.1	0.027*	1.166 (1.018 – 1.336)			
Severe medically compromised	488 (1.6)	13.6	0.017*	1.478 (1.074 – 2.034)			
Unknown	9.070 (28.8%)						
Periodontal condition (DPSI)							
No periodontal problems (score A)	12.650 (40.2%)	6.7	-	1.00			

Table 2. Continued

	No. of restorations	Annual Failure Rate AFR (%)	P-value	Hazard Ratio$_1$ (95% Cnfidence interval) Patient factors included	P-value	Hazard Ratio$_2$ (95% Confidence interval) Patient factors excluded	Percentage difference in HR, with and without patient related factors included
Mild periodontal problems (score B)	7.896 (25.1%)	7.6	0.105	1.116 (0.977 – 1.275)			
Severe periodontal problems (score C)	4.611 (14.7)	10.5	0.014*	1.207 (1.039 – 1.402)			
Unknown	6.315 (20.1%)						
Oral hygiene							
Poor	1.692 (5.4%)	12.7	-	1.00			
Average	10.207 (32.4%)	7.7	0.195	0.872 (0.708 – 1.073)			
Good	7.894 (25.1%)	7.8	0.043*	0.824 (0.683 – 0.994)			
Unknown	11.679 (37.1%)						
Presence of a removable denture							
No	29.816 (94.7%)	7.3	-	1.00			
Yes	1.656 (5.3%)	16.9	<0.001*	1.712 (1.138 – 2.038)			
Caries risk and parafunctional habits							
Low caries risk without parafunctional habits	5.554 (17.6%)	6.0	-	1.00			
Low caries risk with parafunctional habits	1.754 (5.6%)	8.0	0.070	1.207 (0.985 – 1.480)			
High caries risk without parafunctional habits	6.613 (21.0%)	9.3	<0.001*	1.572 (1.331 – 1.855)			
High caries risk with parafunctional habits	2.143 (6.8%)	11.8	<0.001*	1.687 (1.405 – 2.026)			
Unknown	15.408 (49.0%)						

Table 2. Continued

	No. of restorations	Annual Failure Rate AFR (%)	P-value	Hazard Ratio$_1$ (95% Cnfidence interval) Patient factors included	P-value	Hazard Ratio$_2$ (95% Confidence interval) Patient factors excluded	Percentage difference in HR, with and without patient related factors included
Tooth and restoration characteristics N = 31 472							
Arch							
Mandible	14.050 (44.6%)	8.3	-	1.00	-	1.00	
Maxilla	17.422 (55.4%)	7.4	0.578	0.974 (0.886 – 1.070)	0.950	1.003 (0.914 – 1.101)	
Tooth type							
Premolar	11.626 (36.9%)	6.5	-	1.00	-	1.00	
Molar	19.846 (63.1%)	8.5	<0.001*	1.383 (1.245 – 1.537)	<0.001*	1.311 (1.181 – 1.456)	-5.21%
Number of surfaces							
2	17.218 (54.7%)	6.4	-	1.00	-	1.00	
3	8.335 (26.5%)	9.3	<0.001*	1.333 (1.188 – 1.496)	<0.001*	1.344 (1.199 – 1.507)	0.82%
≥4	5.919 (18.8%)	10.0	<0.001*	1.345 (1.168 – 1.548)	<0.001*	1.366 (1.188 – 1.571)	1.61%
Endodontic treatment							
No	30.000 (95.3%)	7.2	-	1.00	-	1.00	
Yes	1.472 (4.7%)	19.2	<0.001*	1.890 (1.600 – 2.233)	<0.001*	2.078 (1.767 – 2.444)	9.95%
Used restorative material							
Clearfil Majesty ES-2 (Kuraray, Osaka, JPN)	12.566 (39.9%)	8.1	-	1.00	-	1.00	
Clearfil APX (Kuraray, Osaka, JPN)	13.342 (42.4%)	5.5	<0.001*	0.698 (0.578 – 0.842)	<0.001*	0.692 (0.574 – 0.834)	-0.79%
Other composite resin	4.854 (15.4%)	6.7	0.004*	0.768 (0.640 – 0.921)	0.003*	0.763 (0.636 – 0.914)	-0.69%
Glass ionomer	638 (2.0%)	30.0	<0.001*	4.073 (3.118 – 5.319)	<0.001*	4.395 (3.416 – 5.653)	7.91%
Compomer	15 (0.1%)	-	0.029*	4.062 (1.152 – 14.319)	0.019*	4.224 (1.273 – 14.010)	3.98%
Amalgam	57 (0.2%)	-	0.061	1.884 (0.971 – 3.656)	0.057	1.930 (0.979 – 3.802)	

Table 2. Continued

	No. of restorations	Annual Failure Rate AFR (%)	P-value	Hazard Ratio$_1$ (95% Cnfidence interval) Patient factors included	P-value	Hazard Ratio$_2$ (95% Confidence interval) Patient factors excluded	Percentage difference in HR, with and without patient related factors included
Used adhesive material							
Photobond	8.686 (27.6%)	7.3	-	1.00	-	1.00	
SE Bond	12.645 (40.2%)	8.6	0,038*	1.229 (1.011 – 1.493)	0,040*	1.224 (1.010 – 1.485)	-0.73%
SE Protect	4.062 (12.9%)	9.1	0,150	1.198 (0,936 – 1.532)	0.137	1.204 (0,942 – 1.539)	
Other adhesives	1.332 (4.2%)	8.0	0,226	0,782 (0,525 – 1.165)	0.265	0.801 (0.542 – 1.183)	
Unknown	4.747 (15.1%)						
Diagnosis current restoration placement							
Caries	18.948 (60.2%)	6.7	-	1.00	-	1.00	
Fracture / Wear	7.395 (23.5%)	10.4	<0.001*	1.489 (1.313 – 1.689)	<0.001*	1.352 (1.196 – 1.527)	-9.24%
Other diagnosis	3.424 (10.9%)	8.6	0.017*	1.219 (1.036 – 1.435)	0.340	1.081 (0.921 – 1.268)	-11.36%
Unknown	1.705 (5.4%)						

Patient related factors

Children and adolescents showed the longest restoration survival, while for elderly a shorter survival was found. Restorations placed in medically compromised patients or patients with considerable periodontal disease were more susceptible for failure. A high caries risk (HR=1.572) and presence of parafunctional habits (HR=1.207) resulted in a higher risk for restoration failure, which further increased for patients having both of these risk factors (HR=1.687). The Kaplan Meier graphs of these four risk groups are shown in figure 1. The presence of a partial or full removable denture also strongly compromised restoration survival.

Comparing the hazard ratios from the Cox regression with and without individual patient factors included, showed that the effect of age of the patient on restoration survival increased when other individual patients' factors were eliminated from the regression.

Table 3 shows that almost 78% of all restorations within the high caries risk group were placed due to caries. Moreover, almost 46% of all restorations within the group of patients with parafunctional habits were placed due to fracture or wear (χ^2-tests: $p<0.001$).

Tooth/restoration related factors

Restorations in premolars showed better survival than those in molars (HR 1.383). Most restorations were 2-surface restorations, and the AFR_2 and HR increased with increasing number of surfaces. AFR_2 for non-endodontically treated teeth was 7.2%, while this was 19.2% for endodontically treated teeth (HR=1.890). The highly filled composite resin APX (Kuraray Noritake, Osaka, JPN) showed the lowest AFR_2 (5.5%) and lowest risk for failure in the Cox regression. Restorations placed with the 3-step etch-and-rinse adhesive Photobond/SA Primer (Kuraray Noritake, Osaka, JPN) performed better than those placed with self-etching SE Bond (HR=1.229). Moreover, restorations placed due to fracture were more prone to fail compared to restorations placed due to caries (HR=1.489). Table 4 shows that the most frequent diagnosis for an intervention on a restoration placed due to caries, is an endodontic treatment (χ^2-tests: $p<0.001$). Restorations that were placed due to fracture or wear, most likely failed due to fractures or wear again (χ^2-tests: $p<0.001$).

Comparing hazard ratios from the Cox-regression with and without individual patient factors included, showed a divided effect on tooth and restoration related factors. The influence of an endodontic treatment on restorations survival increased when patient characteristics were excluded, while the effect of the diagnoses decreased.

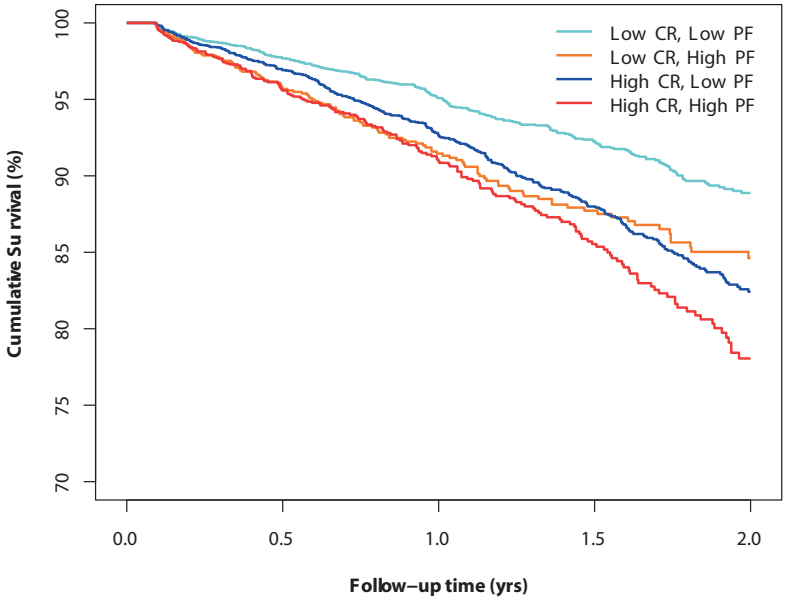

Figure 1. Survival graph of restorations divided by caries risk and presence of parafunctional habits.

Table 3. Percentages of the diagnoses of current restoration placement among the different risk groups (caries and parafunctional habits).

Risk assessment / Diagnosis current restoration placement	Caries	Fracture/wear	Other
Low caries risk without parafunctional habits	51.1%	32.5%	16.4%
Low caries risk with parafunctional habits	38.8%	**45.9%**	15.2%
High caries risk without parafunctional habits	**77.8%**	14.0%	8.2%
High caries risk with parafunctional habits	64.9%	26.6%	8.5%

Table 4. Percentages of the diagnoses of current restoration placement related to the diagnosis of the first intervention.

Diagnosis current restoration / Diagnosis 1st intervention	Caries	Fracture/Wear	Endo	Other
Caries	20.2%	13.8%	**24.4%**	11.6%
Fracture/wear	18.6%	**51.2%**	12.0%	18.2%
Other	14.1%	21.0%	36.9%	28.0%

Discussion

This is the first large cohort study practice based study which extensively evaluates the clinical performance of direct restorations related to a wide variation of potential risk factors. The results showed that the operator, individual patient risk factors such as, age, general health score, periodontal status, caries risk and risk for parafunctional habits, tooth related factor and the diagnosis of the restoration are influencing direct restoration survival.

In this study we were capable of extracting extensive data from the patient files. However, many EPFs were incompletely documented resulting in missing data, which is a limitation of this study. Traditionally EPFs in dentistry were mainly used for billing purposes and data included were limited to tooth number and included surfaces as obligatory data. For this study operators were invited and stimulated to complete EPFs with risk assessment, applied materials and diagnosis of the restoration. As could be expected, dentists did not succeed in collecting all required data for all patients and treatments. The imputation of missing data as performed in this analysis was considered the best choice for dealing with this shortcoming. Performing analyses on complete cases only, is likely to result in exclusion bias and in loss of power.

Still we have to be careful in interpreting results as many grounds for bias are included, like differences between practitioners in risk-assessments, treatment choices, handling EPFs, operator and evaluator being the same person etcetera. Moreover, this study with a relatively short observation time may suffer from ''data pollution'', caused by temporary restorations and specific declaration aspects, related to the reimbursement system in the Netherlands. Especially for research purposes, calibration and accurateness among operators should be done more extensively, but we have chosen for a gradual process of dentists being stimulated to improve their assessments and clinical handling based on the results of their own work.

The main finding of this study is that a plethora of risk factors, especially patient related variables, are associated with restoration failure. In previous studies several of these risk factors have been identified like SES [8], general health, periodontal status [24], oral hygiene [25], high caries risk [4, 25], and parafunctional habits [4, 26]. Moreover, restoration size [27, 28] and presence of an endodontic treatment [11] have been found as risk factors for survival.

A wide range in operator $AFRs_2$ were found, varying between 3.6% and 11.7%, an effect that is confirmed in the Cox regression. This is remarkable keeping in mind that all included dentists are above average motivated to provide high quality care. As indicated

in our previous retrospective study [28], the observed differences may be related to operator skills, clinical experience, sex, age, but it could also be related to practice organization, intervention choices by the dentists and different patient needs and demands. The amount of dentists was too low to investigate dentist related variables like age, graduation of graduation, place of graduation, etcetera. More extensive data collection and further research is needed on these aspects.

An interesting finding is that by leaving out the patient related risk factors, remaining risk factors considerably changed in their effect and significance. Many risk factors seem to be interrelated and their effect changes depending from the other risk factors in the analysis. Illustrative is the effect of SES, that demonstrated significance between high and low SES in the absence of patient related risk factors in the analysis (table 2), suggesting the excluded variables are incorporated in the SES. Excluding patient factors, the effect of the operator increased suggesting that profiles of the patients were different among practitioners, such that the dentist effect described in the previous paragraph could also be due to some patient related risks that were unmeasured or not yet identified. These findings enforce the need to identify record and include as many potential risk factors in the statistical analysis.

In this study, there was a clear relation between the diagnosis for restoration failure and the respective risk group and diagnosis of the first intervention as shown in tables 3 and 4. This indicates that the risk assessment as performed by the GDPs makes sense and dentists are able to identify these risks, although differences among dentists are likely to occur. The further increased failure rate when both parafunctional habits and caries were present, was also demonstrated by van de Sande et al. [4]. On the other hand, deep caries lesions when restored may result in early failure due to pulpitis and endodontic treatment which is a well known early failure in restorative dentistry [10]. Therefore the considerably high amount of endodontic failures related to caries seems logical and related to the short observation time of the present study.

Generally, this study showed a considerable higher failure rate then what is found in many controlled clinical studies. Although we should take into consideration that pressure of routine general dentistry could have reduced quality of placed restorations, a likely factor that explains the higher failure rate is that 65.4% of the patients assessed on risk factors are scored as high risk for caries or/and parafunctional habits. Another study based on the same patient population [29] also found that the majority of restorative work by these practitioners is performed on high caries risk patients. Much higher AFRs can be expected, as for controlled trials in university clinics where these high risk patients are

often excluded [1]. Signori et al. also showed that many restorations replaced due to caries, were indeed having caries lesions in need for restorative treatment. Some discoloured margins might be over diagnosed as caries, but we expect this number will be limited.

Differences between restorative materials were also identified in this study, especially compomer and glass ionomer restorations showed a shorter survival compared to composite restorations. However, amalgam was hardly used anymore (n=57), and compomer and glass ionomer were often used for temporary fillings. Future analysis with an extended observation time focussing on composite restorations, may show more accurate survival data and would be more appropriate to discuss at that moment.

This study demonstrated that a wide variation of risk factors on practice, patient and tooth level influences the survival of class II restorations. To provide personalized oral health care, it is important to identify and record potential risk factors and adjust a treatment to the patient needs. Further clinical studies on dental treatment results should preferably include these risk factors in data collection and analysis. Especially for future randomized clinical trials on specific questions like e.g. comparison of two materials, it seems imperative to include these patient variables and deal with the risk factors in a multi variable analysis. As an alternative, patients with specific risk factors could be excluded in order to create a homogeneous patient population, but this might reduce the clinical relevance of the study.

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Chapter 5

The differences between three performance measures on dental restorations, clinical success, survival and failure: a matter of perspective

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Submitted

Abstract

The aim of this retrospective methodology study was to investigate the influence of using different definitions for restoration failure and inclusion criteria on restoration longevity expressed in AFR. EPF from fifteen general dental practices were used for collecting the data for this study. From the EPF, 321,749 composite restorations placed in 52,245 patients by forty-seven GDPs between January 2000 and December 2011 were included. Kaplan-Meier statistics were applied and mean AFRs over 2, 5 and 10 years were calculated. The effect on the AFR of using different levels of failure: based on Claims data (CD), Success (SUC), Survival (SUR) and different inclusion criteria of tooth/restoration variables were reported. Highest AFRs were found for level CD, in which every intervention was considered as failure, and the lowest AFRs for level SUR in which repairs and an endodontic treatments were not considered as a failure. AFRs increased when the observation period prolonged especially for SUR, followed by SUC and CD. An overview of long-term survival studies showed a wide variation in study design, performed clinical examination (USPHS criteria or GDP), number of restorations included, description of restoration failure and found AFRs for CD, SUC and SUR

Introduction

Many clinical studies have been published on the performance of dental restorations in which longevity is established and considered as an indicator for the quality of care delivered. For appropriate survival analysis of a population of restorations, it is necessary that for every restoration the date of placement is available. Moreover, as an endpoint of restoration survival, it is either needed to have the date of failure, or the end of the observation period (for not failed restorations). As an outcome measure, preferably annual failure rate (AFR) is used, as it can be calculated for all observation times. Whereas the alternative, median survival, can only be calculated after at least 50% of the restorations are failed [1].

However, the definition of restoration failure may vary, depending on the perspectives and interests of different stakeholders involved in patient care. A patient will probably consider a restoration as failed when function and aesthetic appearance is not acceptable anymore, resulting in a visit to the dentist asking for an intervention. For the dentist aesthetic problems may not always count as failures, since they do not compromise the health of the tooth. However, the dentist may also consider as failures smaller defects, which the patient did not notice, when they may pose a risk for a more catastrophic failure, such as secondary caries in restorations with marginal gaps. Financial considerations may reduce the patient's tendency, but increase the dentist's tendency to indicate failures. A dental researcher performing a clinical trial on a newly developed material will be interested to distinguish small details between materials within a short observation period and is likely to consider small imperfections as failures. From the point of view of institutions involved in the financing of dental health care, such as government and insurers, a failure may be defined as the moment a similar or increasingly complicated treatment in the same tooth has to be paid for. These differences have a profound effect on the reported outcomes of different types of restoration performance studies.

Studies aiming to evaluate clinical performance of new materials and techniques, are often performed under controlled circumstances within university clinics and using detailed criteria [2]. When examined by independent observers these restorations can be considered as failed, based on criteria such as 'discoloration of margins' or 'exposed dentin surface'. However, these restorations are still functioning well for the patient and may do so for several years to come. Studies evaluating restorations placed by general practitioners, often consider a new (restorative) intervention as failure of the previous restoration [3, 4, 5] which is biased by the clinical judgement of either the same dentist who placed the restoration, or a new operator and will vary among dentists [6, 7].

For studies based on insurance data, a new intervention on the same tooth will be the definition for failure [8, 9]. However, a new restoration is not necessarily related to the previously placed one. It is unknown to what extent these differences in 'endpoints' for a longevity analysis influence outcome.

Currently repair instead of replacement is considered a preferable treatment option for a defective restoration [10]. Repair has been shown to be able to increase restoration survival [11, 12, 13], when the repair restorative intervention is not considered as a failure in the analysis. The same is the case for endodontic treatment which from one perspective can either be considered as a failure related to the restoration or not. Anusavice described this conflicting phenomenon for indirect restorations, where especially different terminology of chipping and performed endodontic treatments complicated the classification of success and failure of crown and bridge restorations [14]. He recommended, for indirect restorations, to define success (no intervention on the placed restoration), survival (restoration still in place and functioning, but repaired, recemented or endodontically treated) and failure (restoration replaced or tooth extracted). For direct restorations these criteria for success, survival and failure are not commonly used, which complicates comparison of survival rates for direct and indirect restorations.

In countries with dental service that is covered by insurance reimbursement, large datasets of claims data from dentists may be available and can be used for longevity calculations [9, 15]. Furthermore, Electronic Patient Files (EPFs) are implemented in many countries in general dental practices, and big data on restoration properties, patient related variables and dates of placement, replacement and censoring, can be collected and analysed [3, 5, 16]. To improve quality of survival studies and to be able to compare outcomes of longevity studies, it is important to understand what the influence of different definitions of restoration failure on the calculated longevity is. The aim of the present study was to investigate the influence of using different endpoint definitions and inclusion criteria in restoration longevity analysis, on the outcome expressed in Annual Failure Rate (AFR).

Materials and Methods

Inclusion and data collection

An earlier described database was mainly used [16] with data on direct composite restorations, placed between January 2000 and December 2011 in permanent teeth. The data were digitally extracted from the EPF, transformed into an Excel data file and sent to the research group using an application designed by Exquise®, Kwadijk, NL. Data were anonymous and coded, only the practitioners held the code list for their own patients. Practitioners with less than 500 restorations and restorations with missing data on restorative material were excluded. Design and protocol were approved by the local ethics committee, METC (CMO Arnhem-Nijmegen file nr. 2013/483).

Outcome parameters and independent variables

Date of restoration placement, date of last check-up visit of the patient and date and type of re-intervention were recorded. When no intervention on a restoration was performed, the restoration was considered successful and censored at the last check up date. Different levels of failure were defined:

Level Claims Data (CD). This level was defined as follows:

- Each intervention on the same tooth is considered as failure, with the exception of intervention on t = 0.

Level Success (SUC). According to Anusavice [14] success is defined as a restoration on which no intervention has taken place. This level was defined as follows:

- A restoration placed in the same tooth including *one or more* surfaces of the previous restoration was considered as a failure.
- Extraction or endodontic treatment were considered as failure.

Level Survival (SUR). According to Anusavice [14] survival is defined as a restoration that is still functioning and (partially) in place. This level was defined as follows:

- Only restorations placed in the same tooth including *all* surfaces of the previous restoration were considered as a failure. As a result, repairs on restorations are not considered as a failure.
- Extraction was considered as failure.
- Endodontic treatment was considered as censoring.

On tooth/restoration level, tooth number (FDI system, Fédération Dentaire Internationale) and number of restored surfaces were recorded. Based on the tooth number, teeth were divided into anterior (incisors and canines) and posterior teeth (premolars and molars).

For the SUR and SUC analyses, data sets were refined based on the following criteria:

- To exclude temporary restorations, restorative interventions in the first month were ignored and the observation was censored.
- When a MO restoration was placed as the first restoration and the intervention treatment was a DO restoration, analysis for the initial restoration was censored as many MO and DO restorations in posterior teeth are likely independent (box type) restorations. Also for MBP and DBP class III/IV restorations in anterior teeth, this exception was made.
- When a crown was placed within 1.5 year after initial direct restoration, this restoration likely served as base for a crown placement and was censored. Crown placement after more than 1.5 year service time of a direct restoration was considered as failure.

Statistical analysis

Statistical analyses were performed with SPSS 25. Longevity of restorations was explored with survival tables and Kaplan Meier graphs. Out of the survival tables, mean Annual Failure Rates over 2, 5 and 10 years (AFR_z) were calculated according to the formula: $AFR_z\,(\%) = 1 - \sqrt[z]{x} * 100$, in which 'x' level of survival and 'z' the years of observation. The effect on the AFR of using different levels of failure and different inclusion criteria of tooth/restoration variables (anterior/posterior restorations and 1 surface / ≥2 surface restorations) were calculated.

Results

Restorations placed by 47 GDPs working in 15 practices were included in the dataset. Before analysis, restorations were excluded due to missing data on restorative material or treated surfaces (n=14,313) or being placed by practitioners contributing with less than 500 restorations (n=1,542). 321,749 direct composite restorations were included in the final dataset placed in 52,245 patients (25,171 male; 27,074 female; age 5 - 94 years; mean age 37.2 years). The mean number of included restorations per patient was 6.2 (95% CI; 5.3-7.0). The observation period varied between 0 and 12 years (mean observation time 3.7 years). Most restorations were placed in the posterior region and included ≥2 surfaces. The annual failure rates (AFRs) after 2, 5 and 10 years for the different levels of failure and inclusion criteria, are shown in table 1.

Table 1. AFR_2, AFR_5 and AFR_{10} by 3 different levels of failure and inclusion of different tooth/ restoration related variables.

Included variables	N (%)	Failure criteria*	AFR (%) 2 years	AFR (%) 5 years	AFR (%) 10 years
All restorations	321,749 (100)	CD	4.9	5.1	5.4
		SUC	4.2	4.7	5.0
		SUR	2.4	3.1	3.6
Anterior restorations	100,224 (31.1)	CD	4.9	5.1	5.2
		SUC	4.2	4.8	5.1
		SUR	3.1	3.7	4.0
Posterior restorations	221,525 (68,9)	CD	5.0	5.1	5.4
		SUC	4.1	4.6	5.0
		SUR	2.1	2.8	3.4
1 surface restorations	135,000 (42.0)	CD	4.5	4.8	4.9
		SUC	4.0	4.6	4.8
		SUR	3.4	4.2	4.5
≥2 surface restorations	186,749 (58.0)	CD	5.3	5.4	5.7
		SUC	4.3	4.7	5.2
		SUR	1.7	2.3	2.9
Posterior & ≥2-surface restorations (Class II)	155,056 (48.2)	CD	5.2	5.3	5.6
		SUC	4.1	4.5	5.0
		SUR	1.5	2.2	2.9
Anterior & ≥2-surface restorations (Class III & IV)	31,693 (9.9)	CD	5.9	5.9	6.0
		SUC	5.1	5.5	5.9
		SUR	2.3	2.7	3.0

*CD = Based on claims data, SUC = based on success, SUR = based on survival (Anusavice et al., 2012)

Influence of level of failure and excluding tooth/restoration related variables

Overall, the highest AFRs were found for level CD (Failure based on Claims Data) and the lowest AFRs for level SUR (Survival) in which repairs and an endodontic treatment were not considered as a failure. This result is illustrated in the survival graph in figure 1, showing the overall restoration survival for the three different levels of failure. AFRs increased when the observation period was longer especially for SUR, followed by SUC and CD. Comparing posterior and anterior restorations, the AFR for CD was higher for posterior teeth than for anterior teeth, while the AFR for SUC and SUR was lower for posterior teeth. For one surface restorations, differences between CD, SUC and SUR are smaller than for larger restorations (at least two surfaces). AFRs of CD and SUC for one surface restorations were lower than the AFRs of CD and SUC for larger restorations. However, the AFRs of SUR were lower for larger restorations compared to one surface restorations. For class II composite restorations, the 10–year AFRs were 5.6% when based on claims data, 5.0% when based on success and 2.9% when based on survival. For class III & IV composite restorations the 10–year AFRs were higher for all levels of failure, 6.0% when based on claims data, 5.9% when based on success and 3.0% when based on survival.

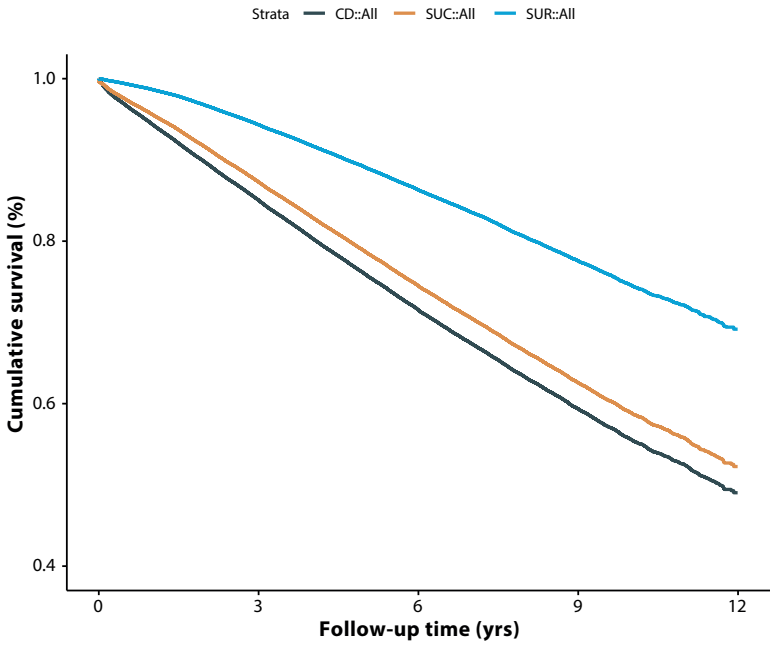

Figure 1. Survival graph of restorations for the levels of failure CD, SUC and SUR.

Comparison outcomes of longevity studies

In order to put findings in perspective a description of studies, published in the last 10 years, evaluating longevity of composite restorations with a minimum follow up of 3 years and at least 100 included restorations, is shown in table 2. This table shows variation in study design, performed clinical examination, number of restorations included, description of restoration failure and AFRs for CD, SUC and SUR. Overall, highest AFRs are found for studies based on claims data. AFRs defined on SUC are higher compared to AFRs defined on SUR

Table 2. Descriptive analysis on studies evaluating longevity of posterior composite restorations for at least 3 year follow up and ≥100 restorations included.

Author	Year publication (country)	Study design	Clinical evaluation	Anterior, Posterior or all included	N restorations	AFR_x (%) success (over x years)	AFR_x (%) survival (over x years)	Repair failure success / survival (Y/N)	Endodontic treatment failure success / survival (Y/N)	Prosthodontic treatment failure success / survival (Y/N)	Extraction failure success / survival (Y/N)
Present study	*2018 (NL)*	*RS*	*Dentist*	*All*	*254,896 / 103,437*	5.0_{10} / $5,1_{10}$	3.4_{10} / 4.0_{10}	*Y / N*	*Y / N*	*Y[¶] / Y[¶]*	*Y / Y*
Reported AFR based on CD											
Lucarotti et al.*[9]	2018 (UK)	RS	Dentist	All	3,504225	10.0_5 8.1_{10} $6,9_{15}$	Na	Y / -	Y / -	Y / -	Y / -
Raedel et al.[15]	2017 (GER)	RS	Dentist	Posterior	18,406,756	$5,0_4$ / $6,3_4^{\#}$	Na	Y / -	N / -	Y / -	Y / -
Raedel et al.[8]	2017 (GER)	RS	Dentist	All	17,024,344	$9,4_4$ – $13,6_4^{\wedge}$	Na	Y / -	N / -	Y / -	Y / -
Reported AFR based on SUC											
Bernardo et al.[32]	2007 (POR)	RCT	Dentist	Posterior	892	$2,2_7$	Na	Y / -	N / -	N / -	N / -
Collares et al.[33][!]	2017 (NL)	RS	Dentist	Anterior	72,196	$4,7_{10}$	Na	Y / -	Y / -	Y / -	Y / -
Kubo et al.[34]	2011 (JAP)	RS	USPHS[mod]	All	503	1.9_{10}	Na	Y / -	Y / -	N / -	Y / -
Laske et al.[16][!]	2016 (NL)	RS	Dentist	All	70,869	4.4_{10}	Na	Y / -	Y / -	Y / -	Y / -
Laske et al.[3][!]	2016 (NL)	RS	Dentist	Posterior	188,683	4.6_{10}	Na	Y / -	Y / -	Y / -	Y / -
Lindberg et al.[35]	2007 (SWE)	PS	USPHS[mod]	Posterior	135	1.1_9	Na	Y / -	Y / -	N / -	N / -
Mahmoud et al. [30]	2014 (EGY)	RCT	USPHS[mod]	Posterior	156	1.5_3	Na	Y / -	Y / -	N / -	N / -
Mahmoud et al. [31]	2014 (EGY)	RCT	USPHS[mod]	Posterior	160	0.9_3	Na	Y / -	Y / -	N / -	N / -
Opdam et al.[36]	2007 (NL)	RS	Dentist	Posterior	1,955	1.7_5 1.9_{10}	Na	Y / -	Y / -	N / -	Y / -
Opdam et al.[37]	2007 (NL)	RS	Dentist	Posterior	376	1.4_9	Na	Y / -	Y / -	N / -	Y / -
Opdam et al.[4]	2010 (NL)	RS	Dentist	Posterior	747	1.4_{12}	Na	Y / -	N / -	N / -	Y / -
Palotie et al.[38]	2017 (FIN)	RS	Dentist	Posterior	5,169	4.2_{13}	Na	Y / -	Y / -	Y / -	Y / -
Suni et al.[39]	2013 (FIN)	RS	Dentist[%]	All	36,537	$4,3_{10}$	Na	Y / -	? / -	? / -	N? / -
Van de Sande et al.*[40]	2013 (BRA)	RS	FDI	Posterior	306	3.2_5, 2.9_{11} 2.3_{15}	Na	Y / -	Y / -	N / -	N / -
Van Dijken et al.[20]	2011 (SWE)	RCT	USPHS[mod]	Posterior	162	$1,7_4$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[21]	2011 (SWE)	RCT	USPHS[mod]	Posterior	114	$2,3_7$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[22]	2013 (SWE)	RCT	USPHS[mod]	Posterior	118	$2,1_6$	Na	Y / -	N / -	N / -	N / -

Table 2. Continued

Author	Year publication (country)	Study design	Clinical evaluation	Anterior, Posterior or all included	N restorations	AFR_x (%) success (over x years)	AFR_x (%) survival (over x years)	Repair failure success / survival (Y/N)	Endodontic treatment failure success / survival (Y/N)	Prosthodontic treatment failure success / survival (Y/N)	Extraction failure success / survival (Y/N)
Van Dijken et al.[23]	2013 (SWE)	RCT	USPHS^{mod}	Posterior	111	$2,2_6$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[24]	2014 (SWE)	RCT	USPHS^{mod}	Posterior	104	$1,0_3$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al. [25]	2014 (SWE)	RCT	USPHS^{mod}	Posterior	114	$2,1_{10}$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[26]	2015 (SWE)	RCT	USPHS^{mod}	Posterior	153	$1,7_8$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[27]	2015 (SWE)	RCT	USPHS^{mod}	Posterior	196	$1,2_3$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[28]	2016 (SWE)	RCT	USPHS^{mod}	Posterior	183	$1,1_5$	Na	Y / -	N / -	N / -	N / -
Van Dijken et al.[29]	2017 (SWE)	RCT	USPHS^{mod}	Posterior	134	$2,8_6$	Na	Y / -	N / -	N / -	N / -
Reported AFR based on SUC and SUR											
Baldissera et al.[41]	2013 (BRA)	RS	FDI	All	374 / 219	$0,8_{17}$ / $0,7_{17}$	$0,1_{17}$ <	Y / N	Y / Y	N / N	Y / N
Casagrande et al.[13]	2017 (NL)	RS	Dentist	Posterior	59,722	$4,1_{10}$	$2,9_{10}$	Y / N	Y / Y	Y / Y	Y / Y
Da Rosa Rodolpho et al.[42]	2011 (BRA)	RS	FDI	Posterior	362	1.8_{22}	0.8_{22}	Y / N	Y / N	N / N	Y / Y
Fennis et al.[43]%	2014 (NL)	PS	Dentist	Posterior	158	3.1_5	2.5_5	Y / N	Y / Y	Y / Y	Y / Y
Kopperud et al.[44]	2012 (NOR)	PS	Dentist	Posterior	3,276	3.0_4	2.4_4 +	Y / N	N /N	N / N	N / N
Pallesen et al. [45]	2013 (DK)	PS	Dentist	Posterior	4,355	2.1_8	1.2_8 +	Y / N	N /N	N / N	N / N
Rho et al.[19]	2013(KOR)	RS	USPHS	Posterior	138	$4,3_{12,5}$	$1,7_{12,5}$ >	Y / N	Y / Y	Y / Y	Y / Y
Soncini et al.[46]	2007 (USA)	RCT	Dentist	Posterior	753	$3,8_5$	$3,2_5$	Y / N	N / N	N / N	N / N
Wierichs et al.= [5]	2018 (GER)	PS	Dentist	All	192	1.4_{10}	0.6_{10}	Y / N	Y / N	Y / N	Y / Y

*AFRs over different years applicable, not all mentioned here.

= Only endodontically treated incisors, canines and premolars were included.

AFR_4 for interproximal / occlusal surfaces.

^Range of AFR_4 for different restoration sizes (up to ≥4 surfaces included

< Only overall results concerning repair/replacement present.

! When a crown was placed within 1,5 year after initial direct restoration, this restoration likely served as base for a crown placement and was censored. Crown placement after 1,5 year was considered as failure.

% Indirect and direct composite restorations included.

- Results from two different birth cohorts.

+ Described as acceptable restoration, defined as ''minor effects, without need for repair of replacement''.

> AFR survival considering not replaced restorations, but scored with Charlie, as no failure.

Discussion

The present study was performed to investigate the influence of using different criteria and including or excluding restorations in a dataset for restoration survival. For this purpose we used a big dataset retrieved from EPFs of several dental practices limited on direct composite resin restorations. As far as we are aware, this is the first methodological study on the comparison of different definitions of failure and inclusion/exclusion criteria for direct composite restorations expressed in AFR. Results from our analysis and the comparison with the results of previous long-term survival studies, shown in Table 2, will be further discussed.

As expected, the highest AFRs were found when any new restorative intervention on a specific tooth is considered as a failure of the previous restoration, as occurs when claims data are used (CD). Previous studies that used claims data where those from Burke and Lucarotti [9, 17], based on English NHS insurance data, and Raedel et al. [8, 15] based on data from a big German insurance company (Table 2). These studies show higher failure rates varying from 5.0 to 13.6% as compared to studies based on SUC (AFRs varying from 0.9 to 4.7%) or SUR (varying AFR from 0.1 - 3.2%) outcome. The high failure rates in CD studies may be explained from the results of the present study as many relevant inclusion and exclusion criteria that were used to modify the CD dataset into the SUC and SUR dataset were not employed, such as allowing for two independent restorations in the same tooth. Looking at all restorations in the present study, AFRs after 2 years increased from 4.2% (SUC) to 4.9% (CD) which is an increase of 17%. However, for longer observation times this difference decreased, which may be related to short term new claim on restored teeth not being clinical failures but planned treatments, e.g., consecutive treatments in a specific treatment plan. Based on our findings, we would conclude that survival data based on claims data may provide an overestimation of the actual failure rate of restorations, especially when this data is based on a short observation period.

A limitation of our study is that we cannot investigate the influence of dentists claim behaviour, and indirect the Dutch reimbursement system, on the results. As an example, a full composite build up of an anterior tooth can be claimed as two 2-surface restorations or as one 4-surface restoration. For other countries with other claims systems, this may result in different characteristics resulting in other differences between claims data CD and actual SUR and SUC data. Therefore, survival data based on CD should be interpreted with much care.

Especially for direct restorations it is common that in clinical research, restorations showing deficiencies are considered failed, nevertheless some of these restorations are further monitored without repair or replacement. For indirect restorations the difference between interventions leading to restoration or tooth loss and minor interventions resulting in a further clinical service of the restoration, is already more common in survival studies following the recommendations by Anusavice [14]. In our present study, we demonstrated that when an intervention resulted in survival (SUR) and not in failure (SUC), annual failure rates decreased considerably. For all restorations AFRs for 2 and 10 years dropped by 51% and 33%, while for class II restorations this was 71% and 48%, respectively. This effect was greater for larger restorations than for small restorations, which is logical, as for 1-surface restorations only endodontic interventions determine the difference between SUR and SUC as 1-surface restorations could not be identified as repaired from the EPF data. Due to this large difference, we recommend that for both indirect and direct restorations definitions for different level of failures are described (Success and Survival) and reported in all types of clinical trials in order to enable comparison of study results. The fact that repair is considered nowadays as a state-of-art minimally invasive intervention, justifies the separate analysis of these types of treatment.

A further limitation of the study is that we cannot show the differences between failure based on either dentists' judgements or defined criteria (USPHS and FDI) [2, 18]. A previous study of Rho et al. [19] has investigated this aspect and showed that a number of clinically functioning restorations, when evaluated according to these criteria were considered as failed and accordingly, AFRs more than doubled from 1.7 to 4.3%. From an oral health care perspective, we would recommend that only restorations that actually received an intervention should be considered as unsuccessful. Especially the Charlie criteria according to USPHS and FDI definitions include items regarding discolorations, dentin exposure at the outline, absence of proximal contact that do not imply that a restoration is not functioning satisfactorily. Such defects often do not justify a restorative intervention and doing so would lead to overtreatment. For controlled trials evaluating a new restorative material AFRs on actually repaired or replaced restorations would then be reported in the survival analysis, while the USPHS or FDI criteria still can be very useful to identify differences between materials on a more detailed level, such as they have been used in specific trials for material comparison like the studies of van Dijken et al. [10-29] and Mahmoud et al. [30,31]. However, the reported AFRs in these studies are lower and hard to compare with studies based on data from private practice because these studies are often performed in a selected patient group. The studies from table 2 that used different criteria for survival and success showed the same reduction in AFR as the present study.

The present study showed that Claims Data when employed for survival analysis of restorations, most likely result in an overestimation of failed restorations. Secondly, distinguishing Success and Survival for direct restorations and including different restorations related variables lead to significantly different failure rates. Using failure criteria, Success and Survival, in future clinical studies would enable a better comparison of studies as well as demonstrate the impact of more conservative restorative intervention protocols on patient care.

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Chapter 6

Minimally invasive intervention for primary caries lesions, are dentists implementing this concept?

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Abstract

Contemporary minimally invasive treatment concepts for restorative treatment of primary caries lesions includes both a delayed moment of intervention and smaller sized preparations restricted to removal of carious tissue. The aim of this study was to investigate whether these concepts have resulted in a trend toward a more conservative choice made by dentists regarding treatment thresholds and restorative techniques. Results from previous conducted pre-coded questionnaires, developed by Espelid and Tveit, and a recent Dutch questionnaire were collected and analysed. A worldwide trend towards more minimal invasive strategies in operative treatment of caries lesions could not be observed, neither for initiation of operative treatment nor for preparation techniques. However, in some countries changes over time could be assessed, especially in Norway, where a reduction of the proportion of interventions is visible for both occlusal and approximal lesions, indicating that more dentists are postponing intervention until the lesions have progressed into a deeper level. From the Dutch national survey it could be concluded that operators that intervene in an earlier stage of approximal lesions (≤ stage 4), also intervene in an earlier stage of occlusal caries (≤ stage 3) ($p = 0.012$, OR = 2.52, 95% CI 1.22 – 5.22). Generally, it can be concluded that dentists worldwide still tend to intervene operatively at a too early caries stage, although variations exists between countries. A worldwide shift could be observed in the applied restorative material, as composite resin has almost completely replaced amalgam for restoring primary caries lesions.

Introduction

Despite the fact that prevalence of dental caries has decreased over the past decades, it still remains one of the most prevalent diseases worldwide [1]. Dental caries has a great impact on global clinical and economical burden [2, 3] and caries management is a main issue in oral healthcare.

Prior to late 1970's, caries progression in dentin was considered to be a rapid and irreversible process and the concept of arresting caries lesions wasn't well adopted ye [4]. In the early 1980's, studies first showed caries was indeed a slow progressing disease which initiated a more preventive, non-operative concept for its treatment [5, 6]. Nowadays, it is commonly accepted that a low-cariogenic diet and adequate oral hygiene by brushing with fluoride containing toothpaste can control or arrest progressive demineralization and caries lesion progressing [7]. As a result, increased emphasis is placed on the concept that caries should be managed using non-invasive preventive methods as much as possible [4, 16].

However, absence or failure of preventive management will still lead to the need for operative intervention. During the last decades, a minimally invasive treatment concept for caries lesions has been introduced. This includes both a delayed moment of intervention (9) and smaller sized preparations restricted to removal of carious tissue only, instead of the 'extension for prevention' treatment concept. Moreover, the choice of restorative material for restoring caries lesions has changed too, from amalgam towards adhesive tooth-coloured materials, mainly composite resin. The use of adhesive techniques made it possible to use less invasive preparation designs, restricted to removing only carious tissue, abandoning traditional amalgam retentive preparation forms while for proximal lesions saucer shaped preparations were introduced. Tunnel restorations for proximal lesions were explored too, but have been proven to be unsuccessful [10-12]. The decision to intervene operatively on a carious lesion is based on diagnosis by visual and tactile inspection for occlusal caries, while bitewing radiography is mainly employed for diagnosis of approximal caries [13-15]. Based on the presence of discoloured or cavitated fissures and translucencies on radiographs, dentists decide when and how to intervene in a caries lesion. Espelid and Tveit [16, 17] developed questionnaires to investigate dental restorative treatment thresholds and strategies, which is since then employed in several countries showing a wide variation in outcome [18]. There seems to be a tendency towards a more minimally invasive strategy for the treatment of primary caries lesions, but has not been established yet. The outcomes of the surveys should be compared over time, and if possible within countries, as tendencies might be different around the world.

The only available results on restorative decision making on primary caries lesions from the Netherlands date back to 1983 and focused on approximal lesions only [19]. To investigate current Dutch decision making by general practitioners on occlusal and approximal caries lesions, the survey was repeated. The aim of this study is to investigate if there are trends towards a more conservative minimally invasive treatment concept for primary caries as measured by treatment thresholds and the choice of restorative techniques made by dentists.

Materials and Methods

Study population and design

Pre-coded questionnaires developed by Espelid and Tveit [16, 17], have been used in several previous studies around the world. These questionnaires include figures or photographs of different stages of approximal [16] and occlusal lesions [17] and questions about restorative treatment criteria, preparations technique and use of restorative material.

Approximal caries progression was divided into 6 stages; [1] outer half of enamel, [2] inner half of the enamel, [3] enamel-dentin border, [4] outer third of the dentin, [5] outer half of the dentin and [6] inner half of the dentin. Traditional black class II preparation, tunnel preparation or saucer-shaped preparation were the approximal preparation techniques options. Occlusal caries progression was divided into 5 stages; [1] white or discoloured enamel, [2] small cavitation clinically, [3] moderate sized loss of tooth structure, [4] large sized loss of tooth structure, [5] extensive sized loss of tooth structure. For occlusal preparation technique, only carious tissue removal, opening whole fissure or another preparation of preference could be chosen.

Amalgam, glass-ionomer, composite resin, compomer or another material of preference could be chosen as approximal or occlusal restorative material. All of the included studies had the same design and were based on an identical questionnaire, that due to translations into other languages, showed different descriptions of stages of caries, although the figures were identical in all cases. The questionnaires were sent to general practitioners, presenting identical outcome: the chosen decision by the dentist.

To compare them in time and between different countries, the results of the current Dutch questionnaire and of all previous published articles based on these questionnaires were collected and analysed.

Dutch survey

The questionnaire, based on the Espelid and Tveit questionnaire [16, 17], was sent electronically to a sample of 1,050 Dutch dentists in June 2015. Based on the size of the dentist population in the Netherlands of around 8,500 dentists, a desired level of confidence of 95% and an estimated degree of dispersion 30% leads to a required sample size of 311. Taking into account the circumstance that a number of email addresses are not reachable (bouncing) and the experience that 25% - 30% respond to Web surveys, 1.050 Dutch dentists were approached. The sample was drawn randomly by the Royal Dutch Dental Association (KNMT) from the national population of registered dentists, aged 64 years or younger with a known address in the Netherlands. Participation was voluntary and anonymous and no compensation was offered to the respondents. Reminders were sent after 1 week, 3 weeks and 13 weeks. Dentists who were not involved in patient treatment and respondents who did not complete the questionnaire were excluded. Respondents' information regarding gender, years of experience (divided into groups 1-5, 6-15, 16-30, ≥ 31 years) and place of graduation, was collected. The questions from the questionnaire that were included in the national survey and the international studies are shown in Appendix 1.

Design and protocol were approved by the local ethics committee, METC (CMO Arnhem-Nijmegen file nr. 2016-2556).

Statistical analyses were performed with IBM SPSS Statistics version 22.0 (Statistical Package for the Social Sciences; SPSS, Chicago, Ill., USA). Descriptive statistics, analyses with χ^2 - test and logistic regression analyses were performed to characterize the respondent population and present the collected information on occlusal and approximal treatment threshold and restorative management. The significance level was set at 5%. Logistic regression analyses were performed with restoring lesions confined in the outer third of the dentin operatively, up to and including stage 3 in occlusal lesions and stage 4 in approximal lesions, as dependent variable. Dentist's experience, gender, place of graduation, preparation technique and restorative material were set as independent variables. Variables with a p-value ≤ 0.3 in the unadjusted analyses were to be entered into the adjusted logistic regression.

National and international trends

Results of all previous published studies, based on the questionnaire of Espelid and Tveit [16, 17] were gathered. The following background data was extracted from the included studies: year of the conducted survey, year of publication, authors, country, target audience (general dental practitioners or teachers in university) and number of respondents. The evaluated outcomes were: preferred stage of caries intervention (stage 1-5 or 1-6 for occlusal and approximal lesions, respectively); preferred preparation technique (for occlusal lesions: only caries removal, opening whole fissure or other, and for approximal lesions: traditional class II preparation, tunnel preparation or saucer shaped preparation); and preferred restorative material (amalgam, composite, glass ionomer, composite combined with glass ionomer or other).

To evaluate trends in minimally invasive restorative decision making across countries and time, the proportion of dentists intervening at or before stage 3 (occlusal) or stage 4 (approximal), preferring limited preparation techniques (only caries removal for occlusal and saucer shaped preparations for approximal), and preferring composite or amalgam restoration material was plotted against the year of study.

To evaluate possible correlation between countries for occlusal and approximal intervention threshold, preparation technique and preferred restorative material, Spearman correlation coefficient was calculated and scatter plots were drawn.

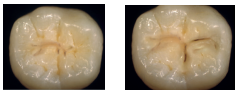
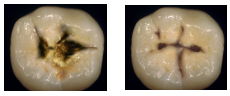
Results

Dutch survey

In total, 280 dentists responded after 3 reminders. The response rate was 27%. Dentists not involved in patient treatment and those who did not complete the questionnaire, were excluded from the statistical analyses (n=26). The mean age of the included dentists (n=254) was 47.69 years (SD=12.3), 34.3% were female and 65.7% male. The individual background characteristics of the respondents and non-respondents are shown in Appendix 2.

As shown in table 1, most dentists would initiate operative treatment in lesions that had progressed into the outer third of the dentin (79.9% for occlusal lesions and 60.6% for approximal). None of the respondents would intervene at stage 1 or wait until stage 5 for occlusal lesions, and only 2 respondents reported waiting until stage 6 for approximal lesions. For approximal lesions 20.5% of dentists would intervene already in enamel lesions and 15% waited until progression had reached the middle third of the dentin. Operators that intervene in an earlier stage of approximal lesions (≤ stage 4), also intervene in an earlier stage of occlusal caries (≤ stage 3). (p = 0.012, OR = 2.52, 95% CI 1.22 – 5.22).

Table 1. Cross table of the number of Dutch respondents selecting specific thresholds for operative treatment in occlusal and approximal caries cases.

				Total (n)
	4	8	1	13 (0 / 13)
	41	130	32	203
	7	16	15	38 (38 / 0)
Total (n)	52 (0 / 7 / 45)	154	48 (46 / 2)	254

As the stages at either end of the spectrum were very rarely chosen these were merged with the adjoining stages for the table. However, the individual numbers are shown in brackets in the cells showing the total numbers.

For occlusal lesions, 188 dentists (74,0%) reported only removing carious tissue, while 62 dentists (24.4%) reported using the traditional whole fissure preparation. The saucer-shaped was the most preferred preparation type (59.1%) for preparing approximal lesions, followed by the traditional Class II preparation (36.2%). The tunnel preparation was only rarely reported (4.7%). Composite resin was preferred by a vast majority of the respondents for both occlusal (92.5%) and approximal (96.5%) restorations. Amalgam was never reported to be the preferred material and GIC and other restorative materials were only rarely preferred.

The results of the regression analyses are shown in Appendix 3 and 4. None of the independent variables was found to have a significant impact ($p < 0.05$) on the restorative threshold for stage 3 of occlusal caries lesions and stage 4 approximal caries lesions and wide confidence intervals were seen. An adjusted analysis was therefore not performed. The odd ratios of place of graduation could not be calculated, due to fact the 2 x 2 tables contain a 0. Therefore this variable can't be used and the p-value from the chi-square test was recorded.

International comparison

The results of all published studies based on the questionnaire [17] of occlusal caries lesion restorative treatment thresholds, preparation technique and proposed restorative material are shown in table 2. The results of all published studies based on the questionnaire [16] on approximal caries lesion restorative treatment thresholds, preparation technique and proposed restorative material are shown in table 3. Stages of lesion depth were described differently in some studies and are marked (*). In the study from Iran [20] it was impossible to choose stage 4 in the questionnaire and this study is therefore difficult to compare with other studies. The studies of Kakudate et al., Gordan et al. and Heaven et al. [21-23] divided the treatment threshold for low- and high caries risk patients. These studies are marked and the results for low risk patients were selected for this study.

Figure 1 shows the correlation between the restoration threshold (stage 3) and the only caries removal preparation for occlusal caries lesions. This plot suggests that there is a strong tendency when dentists are intervening in a later stage of the caries process, they are also more likely to use a minimal invasive preparation technique. However, this result is not statistically significant as the Spearman correlation coefficient (-0.579, p-value: 0.062) did not achieve the significance level set for this study (5%). No association between the stage of intervention and the preparation technique was observed.

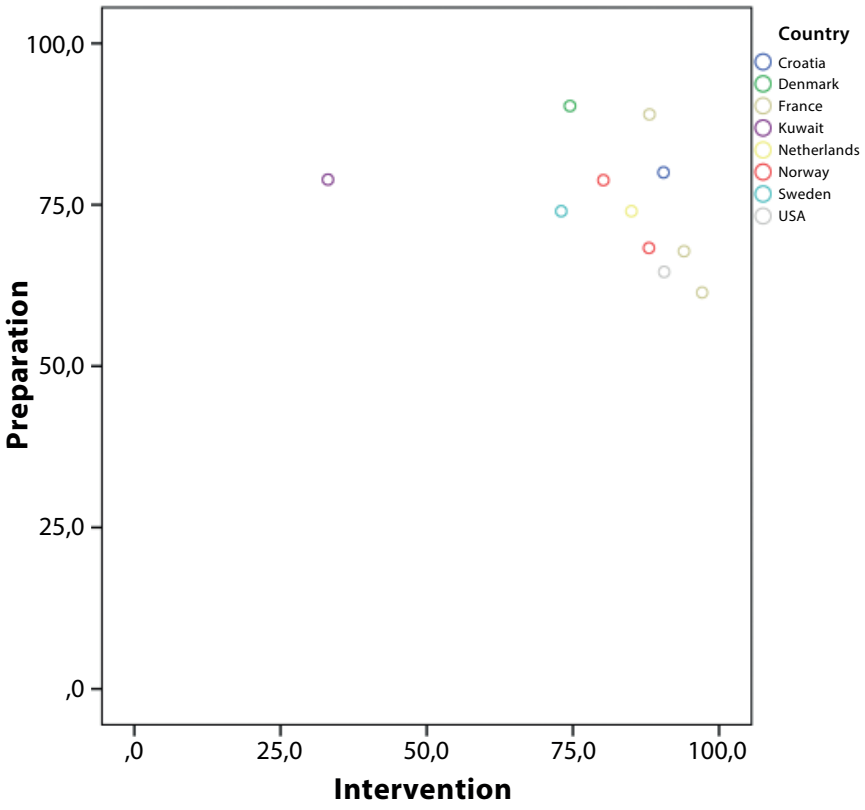


Figure 1. Scatterplot of the percentage of respondents intervening at stage 3 occlusal caries (x axis) and the percentage of respondents choosing only caries removal as the preparation technique (y axis).

Table 2: Results of all published studies based on the questionnaire [Espelid et al., 2001] on occlusal caries lesion restorative treatment thresholds, preparation technique and proposed restorative materials.

Year questionnaire	Year publication	Author	Country	Target questionnaire	N	Stage 1 (%)	Stage 2 (%)	Stage 3 (%)	Stage 4 (%)	Stage 5 (%)	Only caries removal	Opening whole fissure	Other	Amalgam	Composite	GIC	Composite /GIC	Other
1995	2001	Espelid et al. (17)	Norway	General	640	0.5	17.3	70.2	11.5	0.5	68.3	31.7	0	19.9	39.1	22.2	16.1	2.7
1995	2001	Espelid et al. (17)	Denmark	General	173	0	4.6	69.9	24.3	1.2	90.3	9.7	0	52.4	29.2	2.4	14.3	1.8
1996	1999	Mejare et al. (32	Sweden	General	590	0.1	5.9	67.0	26.7	0.3	74	26	0	2.9	71.6	11.4	12.6	1.5
2002	2004	Domejean et al. (28)	France	General	793	2.1	47.8	47.2	2.9	0	61.4	36	2.6	17.3	74.3	7.0	0	1.4
2003	2004	Tubert-Jeanni et al. (29)	France	University	86	0.6	20.1	67.4	11.9	0	89	8	3	8	92	0	0	0
2009	2016	Kopperud et al. (33)	Norway	General	2.375	0.3	12	68	19	0.8	78.8	21.2	0	0	91.9	4.8	1.6	1.7
2012	2013	Heaven et al. + (23)	USA	General	479	1.3	9.4	34.2	47.8	7.3	-	-	-	-	-	-	-	-
2012	2015	Domejean et al. (43)	France	General	770	2.1	37.2	54.7	6.0	0	67.8	30	2.2	7.3	81.6	11.0	0	0.1
N.A.	2012	Baraba et al. (31)	Croatia	University	59	1.5	20	69	8	1.5	80	20	0	2	81	7	10	0
2013	2014	Khalaf et al. (42)	Kuwait	General	185	0	4.3	28.1	43.8	23.8	78.9	21.1	0	9.7	68.7	14.6	5.4	1.6
2013	2016	Rechmann* (27)	USA	General	1,922	1.8	38.9	49.9	7.7	1.7	64.6	31.5	3.9	4.7	94.6			0.7
2015	2017	Laske et al.	Netherlands	General	254	0	5.1	79.9	15.0	0	74.0	24.4	1.6	0	92.5	5.1	0	2.4

+ Results based on low caries risk patients

- Not asked in the questionnaire

^ No distinction was made between composite resin, GIC or combination of both. These choices were gathered under ''tooth coloured restorations''

Percentages in a column may not equal 100 due to rounding

Table 3: Results of all published studies based on the questionnaire [Espelid et al., 1985] on approximal caries lesion restorative treatment thresholds, preparation technique and proposed restorative materials.

Year questionnaire	Year. Publication	Author	Country	Target questionnaire	N	Stage 1 (%)	Stage 2 (%)	Stage 3 (%)	Stage 4 (%)	Stage 5 (%)	Stage 6 (%)	Class II preparation	Tunnel preparation	Saucer shaped preparation	Amalgam	Composite	GIC	Composite /GIC	Other
1983	1985	Espelid et al. (16)	Norway	General	616	2.3	19.1	44.2	30.0	3.9	0.5	-	-	-	-	-	-	-	-
1983	1988	Mileman et al.* (19).	Holland	General	325		10	44	38		8	-	-	-	-	-	-	-	-
1987	1990	Nutall et al.* (37)	Scotland	General	1.127	2.4	3.0	15.6	19.8	47.2	12.0	-	-	-	-	-	-	-	-
1990	1991	Riordan et al. (38)	Australia	General	45	2.2	8.9	28.9	40.0	11.1	8.9	-	-	-	-	-	-	-	-
1992	1994	El-Mowafy et al.* (39)	Canada	General	1.276	1		27	67	5	0	-	-	-	-	-	-	-	-
1995	1999	Tveit et al.*(4)	Norway	General	640		3.6	14.7	62.0	19.2	0.5	28.2	47.5	24.3	15.5	15.8	46.3	22.4	0
1996	1999	Mejare et al. (32)	Sweden	General	590	0.2	2.0	4.5	41.0	51.8	1.5	20.3	47.7	32.0	2.9	56.9	13.7	24.7	1.8
1999	2005	Traebert et al.* (41)	Brasil	General	840	31.5	23.0	24.5	17.9	2.8	0	-	-	-	-	-	-	-	-
2002	2004	Domejean et al. (28)	France	General	793	20.5	35.5	32	11.5	0.5	0	12.0	33.3	54.7	20.5	58.4	12.3	5.5	3.3
2003	2004	Tubert-Jeannin et al.	France	University	86	2.4	19.5	39.1	31	6.5	1.5	2.4	60.7	36.9	8.3	78.6	11.9	1.2	0
2005	2006	Ghasemi et al.* (20)	Iran	General	870	7		24		57	11	-	-	-	-	-	-	-	-
2005-2006	2009	Gordon et al.*(22)	USA	General	500		1.8	39	54	5	0.2	-	-	-	-	-	-	-	-
N.A.	2010	Baraba et al. (30)	Croatia	General	307	10	32	39	18	1	0	32	46	22	4	66	13	17	0
2009	2011	Vidnes-Kopperud et al.* (4)	Norway	General	2.026		0.2	6.8	56.5	35.8	0.7	27.8	3.8	68.4	0	94.9	3.3	1.8	0
2011	2012	Kakudate et al. * + (21)	Japan	General	189	3.7		42.8	42.8	9.1	1.6	-	-	-	-	-	-	-	-
N.A.	2012	Baraba et al. (31)	Croatia	University	59	14.5	19.5	34	30	1	1	17	47	36	0	65	17	6	12
2012	2013	Heaven et al. * + (23)	USA	General	479		1.9	41.8	53.7	2.5	0.1	-	-	-	-	-	-	-	-
2013	2014	Khalaf et al. (42)	Kuwait	General	185	2.2	8.1	7.0	40.0	18.9	23.8	49.2	24.9	25.9	11.4	61.0	14.6	13.0	0
2013	2016	Rechman et al. ^ (27)	USA	General	1,922	2.9	15.1	42.6	33.4	4	2	54.1	0	45.9	6.4	92.6			1
2015	2017	Laske et al.	Netherlands	General	254	0	2.8	17.7	60.6	18.1	0.8	36.2	4.7	59.1	0	96.5	0.8	0	2.8

* Stages differently described compared to [Espelid et al., 1985]

+ Results based on low caries risk patients

- Not asked in the questionnaire

^ No distinction was made between composite resin, GIC or combination of both. These choices were gathered under "tooth coloured restorations"

Percentages in a column may not equal 100 due to rounding

Thresholds for initiating operative treatment

Figure 2a and b shows for each study the proportion of dentists reporting restorative intervention at or before stage 3 occlusal caries lesions and approximal stage 4 lesions. Data from time points at least 10 years apart was available for Norway (1983, 1995 and 2009), France (2002 and 2012) and the Netherlands (1983 and results from the present Dutch survey). In Norway, a reduction of the proportion is visible for both occlusal (88,0% in 1995, to 80,2% in 2009) and approximal (95,6% in 1983, to 80,3% in 1995, to 63,5% in 2009) lesions, indicating that more dentists are postponing intervention until the lesions have progressed to a deeper level. In France a small similar trend could be observed for occlusal lesions (97,% in 2002 to 94% in 2012). For approximal caries lesions in the Netherlands a similar trend could also be observed from 92% (1983) to 81.1% (2015). Relative outliers are visible from studies in 2012 (USA), 2013 (Kuwait) and studies in 1987 (Scotland) and 1996 (Sweden), where occlusal and approximal intervention, respectively, is predominantly postponed until frank cavitation.

Preparation techniques

Figure 2c and d shows for each study the proportion of dentists preferring minimally invasive preparation techniques. In Norway (between 1995 and 2009) and France (between 2002 and 2012), a clear increase (10 to 20%) of the carious tissue removal only method was observed for occlusal lesions. For approximal lesions a very strong trend was observed in Norway: with the reported use of a saucer shaped preparation increasing from 24.3% in 1995 to 68.4% in 2009. In contrast, table 2 reveals that the standard class II preparation was still the most favoured preparation design reported for California and Kuwait even in 2013.

Use of restorative materials

Figure 2e and f shows the preferred restorative material reported in all studies. A linear trend line was drawn for the use of composite resin and amalgam. Across countries a clear increase of the use of composite can be observed, with amalgam becoming almost extinct. Glass ionomer cement use (alone or in combination with composite) was only substantially reported between 1995 and 1999 in Scandinavia.

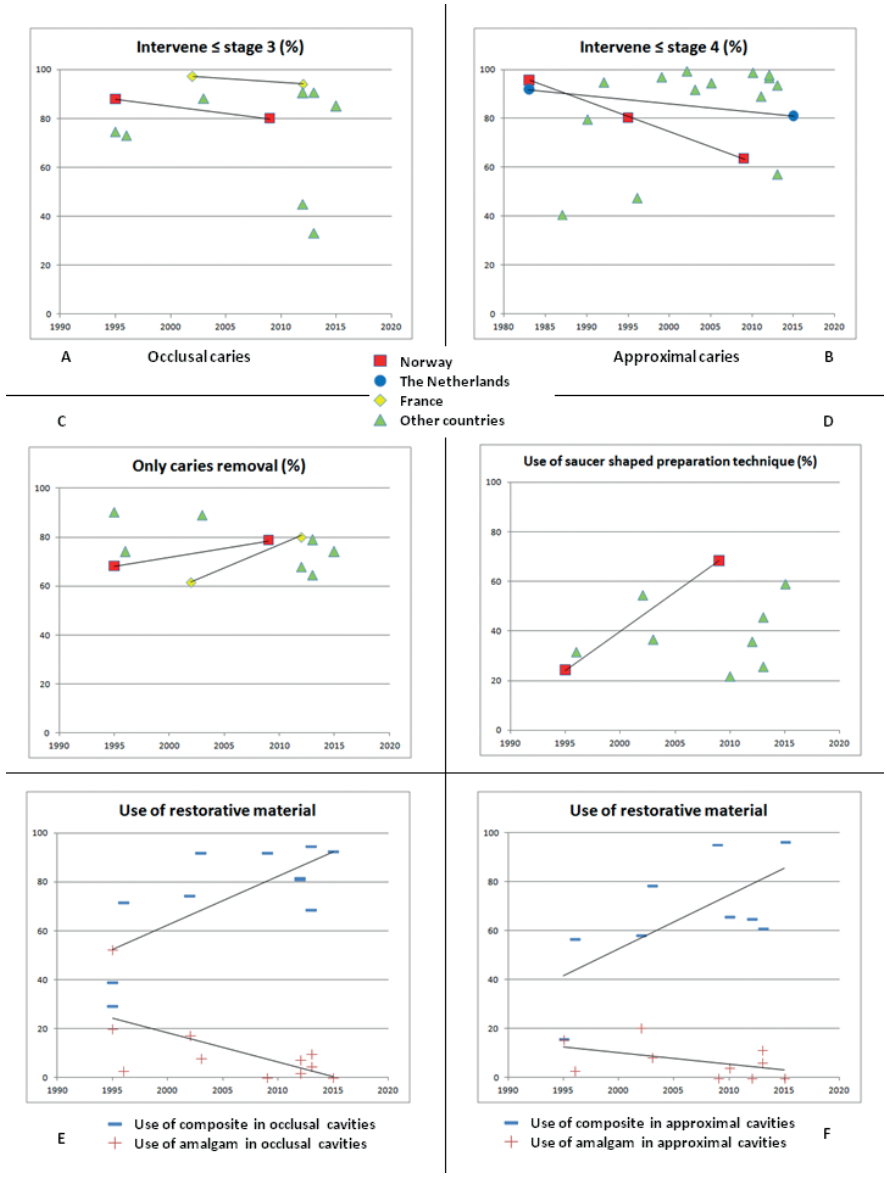


Figure 2. Scatterplots from different studies for restorative threshold (%), minimally invasive preparation technique (%) and the preferred restorative material (%) against the year the questionnaire was administered. a, b For each study, the proportion of dentists reporting restorative intervention at or before stage 3 occlusal caries lesions (a) and approximal stage 4 lesions (b) is shown. c, d For each study, the proportion of dentists preferring only occlusal caries removal (c) and an approximal saucer-shaped preparation (d) is shown. e, f For occlusal (e) and approximal (f) cavities, the proportion of dentists preferring a composite resin or amalgam restoration is shown.

Discussion

The present study aimed to explore a possible worldwide trend towards a more minimal invasive strategy concerning operative intervention on primary caries lesions. For this purpose the results from questionnaires designed by Espelid and Tveit [16, 17] were used. However, as the dates of survey differ considerably over time, caries experience and socio-cultural differences exists among countries and only for a limited number of countries two questionnaires could be compared with an interval of at least 10 years, it is difficult to conclude about worldwide trends. Within these limitations we can strictly state that an international trend towards more minimal invasive strategies in operative treatment of caries lesions could not be observed, neither for initiation of operative treatment nor for preparation techniques. Figures 2 a-d show a scattered landscape mainly due to remarkable differences between countries. For the few cases that we were able to compare results within the same country over time, some trends could be observed which will be discussed.

With the more recent insight that caries is not an infectious disease and (complete) carious tissue removal is not necessary [24], the recommended moment of operative intervention is when preventive measures such as biofilm control, remineralisation strategies and sealing are no longer expected to be successful [24-26]. As a current guideline, cavitated lesions are considered as appropriate candidates for operative intervention [9]. This would also include approximal lesions extending beyond the outer third of the dentine as observed on bitewing radiographs, as these are most likely cavitated, even if cavitation cannot normally be detected clinically [9]. Therefore, in terms of the present questionnaire this would mean that occlusal caries stage 4 and approximal caries stage 5 would be the closest to a minimally invasive 'gold standard' threshold for operative intervention.

The results reported over the years, as shown in figure 2a and b, suggest that there is still a gap between this scientific view on caries management and clinical practice, as the majority of dentists would intervene at stages 3 (occlusal) and 4 (proximal), although in some countries a slow shift towards later intervention can be observed. The most pronounced change was observed in Norway. In 1983, 95,6% of the Norwegian dentists would initiate an operative treatment at the threshold of caries reaching in the outer third of dentin for approximal lesion. Over the years this percentage decreased to 80,3% in 1995 and 63,5% in 2009, clearly indicating that Norwegian dentists are moving towards later intervention. A less clear trend was found in the Netherlands. In 1983, 92% of the Dutch dentists would intervene restoratively in a stage 4 approximal caries lesion, while in 2015 this percentage decreased to 81,1%, indicating that the majority of dentists in the Netherlands still tend to intervene at a too early stage on proximal caries.

As far as intervention for occlusal lesions is concerned, Norway and France both show a slight decrease in early intervention. However, French dentists seems to be more eager to intervene compared to the other studied countries, as both in 2002 and 2012 more than 94% of the questioned French dentists would intervene as soon as caries has reached the dentin. The caries management development in the United States is more difficult to compare, because these surveys are conducted in different states and over a shorter time span, 2005, 2012 and 2013. However, in all three questionnaires more than 90% of studied American dentists would intervene restoratively on caries lesions confined to the outer third of dentin. The scatter plot in figure 1 suggests that there is a tendency when dentists are intervening in a later stage of the occlusal caries process, they are also more likely to use a minimal invasive preparation technique. However, this result was not statistically significant and Kuwait was found as relative outlier. These results could be related to the fact that almost all evaluated countries present a low caries experience. Practising dentists in countries with a high caries prevalence are more used to intervene in a later stage of the caries process and has less possibilities to control progressive demineralization and caries lesion progressing.

These results confirm longstanding differences in preventive orientation, with the Scandinavian countries forming the vanguard for many decades. An explanation for the scattered landscape in decision making especially between countries is difficult to make as several factors may be responsible for this, which have not been investigated before. Differences in reimbursement systems, nationwide caries experience, the age of the dentist population, presence of a public health dental service or the dentist-patient ratio may be responsible for new developments being delayed implemented in a dentist population.

It may be assumed that in the university environment of dental schools, the implementation of new evidence based treatment is likely to precede its spread in general dental practice, and that therefore a younger population of dentists will more likely have been exposed to these changing guidelines. The Dutch dentist population is relatively old, which matches the observation of them still intervening relatively early especially for proximal lesions. Rechmann et al. [27] observed a trend among younger Californian dentists to intervene at a later stage than their older colleagues, which supports this assumption, which may also play a role in the USA results. Differences in occlusal and approximal caries management between teachers in university and general dental practitioners in France and Croatia are found. The threshold of operative treatment for teachers is in a more advanced stage of caries lesions compared to the French general dental practitioners [28, 29]. Also, the more minimal invasive preparation techniques and use of composite is more popular in French universities compared to general dental practices.

In Croatia, no differences were found in restoration threshold or proposed restorative material, but the saucer shaped preparation was more preferred in the university (36%) compared to private practice (22%) [30, 31].

The response rate (27%) in the 2015 Dutch national questionnaire is lower to that obtained for the similar questionnaire in 1983 (77%) and can be seen as a limitation of the results from the present national survey. Nevertheless, the current data provided a general demographic-representative dataset, as shown in Appendix 2. A statistical significant correlation between when to intervene in approximal and occlusal caries was shown (table 1). This indicates that practitioners who are more eager to intervene in an early stage of approximal caries, are also more eager to do so in case of occlusal caries. These findings are in line with previous studies [17, 32, 33].

As far as preparation techniques are concerned, the caries removal only technique has been preferred generally for the past 20 years by more than half of dentists. No overall trend can be observed, although this technique preference grew by 10,5% of dentists over 14 years in Norway and 17% of dentists over 11 years in France. In Norway the preference for a saucer shaped preparation almost tripled to 68,4% between 1995 and 2009. From the results of the last decade, only in Norway and the Netherlands the saucer shaped preparation design is the most favoured technique while overall the traditional class II preparation is still quite popular.

However, one worldwide shift in restoring primary caries lesions, from amalgam towards composite resin could be observed from the present study as illustrated in figures 2 e and f. From the data it becomes clear that composite resin has replaced amalgam as the preferred material for primary caries lesions in the Netherlands, Norway, France and California (USA) where tooth coloured restorations were preferred by more than 90% of dentists. These findings are in accordance with other studies [34,35]. On 1st January 2008 the use of amalgam was banned in Norway and in the most recent surveys [4,33] it was not an option anymore. Glass-ionomer cement reached some popularity as preferred material for restoring primary caries leasions especially in North European countries, although its use decreased overtime. However, it is doubtful whether this shift is driven by a more minimal invasive approach of dentists. It may well be that the WHO recommendation to decrease the use of amalgam and the increased demand of patients for esthetically pleasant restorations is the reason for this [36].

Summarising this overview of the survey results, the following conclusions can be made:

1. Large variations in restorative decisions in what stage to intervene on proximal and occlusal primary caries exist around the world.
2. Generally, dentists decide for operative interventions at a too early stage.
3. In countries where changes over time could be assessed and especially in Norway, an increasing minimal invasive attitude could be observed.
4. Composite resin has almost completely replaced amalgam for restoring primary caries lesions.

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Appendix 1

Questionnaire

Outer half of the enamel	Inner half of the enamel	Enamel-dentin border	Outer third of the dentin	Outer half of the dentin	Inner half of the dentin
1	2	3	4	5	6

Figure 1. Illustration of the different stages of approximal caries progression (stages 1-6)

Case 1 Approximal lesion	These picture illustrates different stages of caries progression on the distal surface of tooth 15 or 25. Imagine a 20-year-old patient with a low caries activity, a good oral hygiene, visits a dentist annually and brushes twice a day with a fluoridated toothpaste
A	Starting in which stage do you think a approximal restoration is indicated? (1-6)
B	Which type of preparation would you prefer for the restoration of the lesion in your chosen stage? (1-3) 1: Traditional Black Class II preparation, 2: Tunnel preparation, 3: Chamfer preparation, saucer-shaped preparation
C	Which restorative material would you prefer for the restoration of the lesion in your chosen stage? (1-5) 1: Amalgam, 2: Glass-Ionomer, 3: Composite resin, 4: Compomer, 5: Other

Table 1. Questions regarding approximal carious lesions

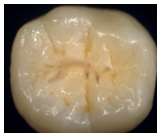	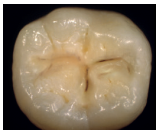		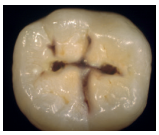	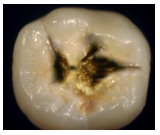
- White or discoloured enamel, no caviation clinically - No radiographic signs of caries	- Small cavitation clinically - No radiographic signs of caries	- Moderate sized loss of tooth structure - Radiolucency in the outer third of the dentin	- Larged sized loss of tooth structure - Radiolucency in the middle third of the dentin	- Extensive sized loss of tooth structure - Radiolucency in the inner third of the dentin
1	2	3	4	5

Figure 2. Illustration of the different stages of occlusal caries progression (stages 1-5)

Case 2 Occlusal lesion	These picture illustrates different stages of caries progression on the distal surface of tooth 15 or 25. Imagine a 20-year-old patient with a low caries activity, a good oral hygiene, visits a dentist annually and brushes twice a day with a fluoridated toothpaste
A	Starting in which stage do you think a occlusal restoration is indicated? (1-6)
B	Which type of preparation would you prefer for the restoration of the lesion in your choosen stage? (1-3) 1: Only carious tissue removal, 2: Opening whole fissure, 3: Other
C	Which restorative material would you prefer for the restoration of the lesion in your choosen stage? (1-5) 1: Amalgam, 2: Glass-Ionomer, 3: Composite resin, 4: Compomer, 5: Other

Table 2. Questions regarding occlusal carious lesions.

Appendix 2

	Non-respondent	Respondent	Total Sample
Sex (df = 1/ p = 0,393 / Cramer's V = 0,027)			
Male	63%	66%	64%
Female	37%	34%	36%
Age on 1st 2015 (df =4 / p = 0,002 / Cramer's V = 0,130)			
29 years or younger	6%	10%	10%
30-39 years	18%	25%	25%
40-49 years	15%	19%	19%
50-59 years	41%	30%	30%
60 years or older	20%	16%	16%
Mean age (df=1 / p = 0,000 / eta^2 = 0,009)	44,5	47,1	45,2
Place of graduation (df =5 / p = 0,065 / Cramer's V = 0,102)			
Amsterdam	39%	33%	37%
Groningen	15%	16%	16%
Nijmegen	25%	22%	24%
Utrecht	10%	17%	12%
Abroad	11%	12%	11%
Year of graduation (df =4 / p = 0,002 / Cramer's V = 0,130)			
1979 or earlier	9%	18%	11%
1980-1989	30%	34%	31%
1990-1999	17%	13%	16%
2000-2009	33%	25%	31%
2010 or later	11%	10%	11%
Mean (df=1 / p = 0,003 / eta^2 = 0,013)	1995,1	1992,1	1994,3
Region of establishment (df =3 / p = 0,251 / Cramer's V = 0,064)			
North	9%	11%	10%
East	20%	21%	20%
South	20%	22%	21%
West	50%	45%	49%
Participation in post graduate education program Iqual (KNMT) (df =1 / p = 0,133 / Cramer's V = 0,048)			
Yes	22%	27%	24%
No	78%	73%	76%
Registered in post graduate education register (df =1 / p = 0,470 / Cramer's V = 0,023)			
Yes	52%	55%	53%
No	48%	45%	47%
Total [#3]	714	227	991
	72%	28%	100%

#1 The sample consisted of 1,050 dentists aged 64 or younger (January 2014) with a known place of residence and / or work in the Netherlands. Those dentists were asked by email to answer the web questionnaire. A total of 55 dentists from the sample were not reached (bouncers: auto reply, wrong or unknown email address). The net sample therefore consisted of 995 dentists.

#2 The 'region of location' is based on the division of the Netherlands into KNMT departments. Here the 'south' region is formed by sections 12, 13 and 14, the 'west' region by sections 5, 7, 8, 9, 10 and 11, the 'east' region by sections 3, 4 and 6. and the 'north' region by the members 1 and 2.

#3 Four people were found to be unidentifiable (completely anonymous)

Representativeness of the collected data: Individual background characteristics of the non-respondents and respondents in the sample from the Dutch survey [#1]

Appendix 3

Independent variable		**Unadjusted**		
	N (%)	*OR*	*95% CI*	*p value*
Gender				
Female	87 (34.3)	1.002	0.485 – 2.073	0.995
Male	167 (65.7)			
Experience				**0.309**
0-5 years	24 (9.4)	4.351	0.543 – 34.900	0.166
6 -15 years	66 (26.0)	1.372	0.539 – 3.491	0.507
16 - 30 years	76 (29.9)	0.769	0.345 – 1.718	0.522
≥ 31 years	88 (34.6)			
Graduation				
Abroad	33 (13)	1.882	0.544 – 6.506	0.318
The Netherlands	221 (87)			
Preparation technique				**0.811**
Open the whole fissure	92 (36.2)	1.282	0.554 – 2.965	0.562
Other	12 (4.7)	-	-	0.590*
Removal of carious tissue only	150 (59.1)			
Filling material				
Amalgam, GIC and others	9 (3.5)	0.457	0.155 – 1.354	0.158
Composite	245 (96.5)			

*Calculated from χ^2 test

Associations between selected variables and the odds of restoring occlusal caries stage III operatively.

Appendix 4

Independent variable		Unadjusted		
	N (%)	*OR*	*95% CI*	*p value*
Gender				
Female	87 (34.3)	1.182	0.602 – 2.320	0.627
Male	167 (65.7)			
Experience				0.120
0-5 years	24 (9.4)	1.567	0.481 – 5.101	0.456
6 -15 years	66 (26.0)	3.134	1.186 – 8.284	0.021
16 - 30 years	76 (29.9)	1.088	0.525 – 2.255	0.821
≥ 31 years	88 (34.6)			
Graduation				
Abroad	33 (13)	-	-	0.003*
The Netherlands	221 (87)			
Preparation technique				0.055
Traditional class II preparation	92 (36.2)	2.496	1.170 – 5.324	0.018
Tunnel preparation	12 (4.7)	0.913	0.234 – 3.559	0.896
Saucer shaped preparation	150 (59.1)			
Filling material				
Amalgam, GIC and others	9 (3.5)	1.899	0.232 – 15.555	0.550
Composite	245 (96.5)			

* Calculated from the χ^2 test.

Associations between selected variables and the odds of restoring approximal caries stage IV operatively


VS
?
AGE

Chapter 7

General discussion

General discussion

Although the placement of direct composite restorations is the most performed dental restorative procedure in general dental practice, practice-based data on restoration survival and risk factors for restoration failure is still lacking. This paucity of research is something we sought to address with this thesis.

In order to analyse larger databases, extracted from the Electronic Patient Files (EPFs) of multiple GDPs in the Netherlands, good cooperation and commitment between GDPs, software companies and researchers proved indispensable. In the first instance, we collaborated with several software companies, but ultimately focussed on one software company which was interested in further development of the digital patient files, to improve data in the EPF as well as facilitating our data collection.

As far as we are aware, in chapter 2 we conducted the first practice-based study reporting on a dataset of more than 350,000 restorations, collected from listed patients within 24 practices. Initially, we collected a dataset of great complexity, which lacked homogenesity. It included anterior and posterior restorations, which we know differ in their failure behaviour. Consequently, we decided to abstain from a multi-variable statistical analysis in this first study. In our subsequent study, we evaluated the clinical performance of class II restorations placed as part of routine everyday restorative care (chapter 3). We supplemented our evaluation with a multi-variable analysis, with limitations, which arose due to the retrospective nature of the dataset and the absence of important restorative data in the EPFs; as inputting this information was not part of the GDPs daily routine. An additional report on the performance of anterior restorations was published outside the scope of this thesis [1]. There was a clear need for EPF software improvement, to help dentists to record such vitally important data for research and quality assessment. Hence, we were able to adjust the EPFs and motivate the practitioners to include necessary patient and restorative data in dedicated areas in the software. This allowed efficient retrieval of anonymized data from the EPF. As a result, a cohort study was started in 2015 which is reported in chapter 4 including defined risk factors such as caries risk, bruxism, general health, periodontal status that were now available from the EPF. Also, the justification underlying restoration placement and materials used were now included in the EPF. After comprehensive software updates, feedback and further training of the participating practices, the recording and analysis of mainly patient-related factors has been further expanded to be used in future studies. Results, limitations, and conclusions from our study will be further discussed, along with avenues for future research.

Operator related variables

Often the dentist is thought to be the most important factor for restoration survival and it is then speculated that the technical quality of the delivered work may be of pivotal interest. In this thesis, a considerable variation in longevity of restorations between the practices was found, with AFRs showing values between 2.3% and 7.9% (chapter 2), between 2.5 and 7% (chapter 3) and 3.6% and 11.4% (chapter 4). Translated into median survival values, this would be a range from 4 to 21 years. Previous longevity studies on direct restorations in general practice [2-4], also showed a wide variation in AFR from 1 to 15%. This thesis confirms that the dentist does indeed play an important factor in restoration survival. The observed differences may be related to operator accuracy, experience and skills, but the dental practices that joined the network at least claimed to be eager to deliver good quality care, a fact which is evident following evaluation of their restorations on bitewing radiographs [5]. Consideration should be given to practice organization, differing patient needs and expectations, differences in patient populations and the dentist's intervention threshold for the clinical decision of repairing or replacing a restoration.

In chapter 2, practice type was found to be a significant factor in restoration survival, larger group practices showed an increased risk of failure compared to solo practices. Working in a group practice might result in check-ups carried out by another dentist from the one who made the restorations, which might result in a higher risk for intervention, as changing dentists was shown to be a risk factor [6, 7]. However, interpretation of practice and dentist influence should be approached with great care as the number of practices and operators is limited and unknown factors at practice level may play a role.

The decision for (re)placing a restoration is based on the clinical expertise of the practitioner during assessment, rather than on strict criteria such as USPHS criteria [8]. It has been shown previously that dentists may make very different decisions when cases of defective restorations are presented to them [6]. This can be seen as operator confounding, and as such is hard to avoid in practice-based research. But as it clearly reflects a clinical reality, it should be included as a factor of interest. We hypothesise that studies on clinical decision making by dentists may result in different "dentist profiles". Those described as being proactive, i.e. more eager to intervene in an attempt to prevent complications, or reactive i.e. those who are inclined to postpone interventions until a complication occurs or patients ask for help [9]. Such profiles may be useful to investigate the influence of treatment thresholds on restoration survival. However, it was impossible to investigate this aspect in the present practice-based network as the number of participating dentists was too low to reach an acceptable statistical power.

Further research, possibly using a decision-making questionnaire distributed to a large number of GDPs, coupled with retrospective analysis of their EPF data, is needed to investigate the influence of treatment decisions on restoration survival.

Regarding restoration longevity, there are some questions arising from this thesis. There was a difference between the longevity of class II restorations from the same practices when data was obtained retrospectively or from the cohort (mean $AFR_{10,retro}$: 4.9% and mean $AFR_{2,\ cohort}$: 7.8%). We have carefully investigated potential software problems and excluded this as the possible cause. We suspect that the cohort study might be polluted with successive restorations that actually constitute one dental restorative treatment. Future studies with a longer observation time will provide insight into this problem. For now, we assume that the retrospective data, as presented in chapter 3, is a realistic view of the survival of class II restorations. In that respect, the median survival of class II restorations would be 12-14 years, which is constitutes very good survival.

Another study based on the same patient population [5] found that much of the restorative work by the dentists is performed in high caries risk patients. The high number of caries diagnoses given as a reason for restoration intervention in chapter 4, confirms that the cohort study in particular, included high risk patients which logically would result in a higher AFR.

Patient related variables

In chapter 4, we found a plethora of patient related risk factors were associated with restoration failure. Many of these factors agree with previous reports, including, SES [10], general health, periodontal status [11], oral hygiene [12], high caries risk [4, 12, 13], and parafunctional habits [13, 14]. An interesting finding is that when omitting the patient related risk factors, the remaining risk factors changed considerably both in their effect and their significance. Many risk factors seem to be interrelated and their effect changes depending on other risk factors in the analysis. Illustrative is the effect of SES and age that demonstrated significance between high and low SES in the absence of other patient related risk factors in the analysis. Using age as an example, we found in chapter 3 that restortions in children (5-12 yrs) and the elderly (71-96 yrs), showed a higher risk of re-intervention as compared to the young-adult group. However, both age groups may be expected to have a relatively high caries risk. Moreover, the older age group often already has a compromised dentition with missing teeth and large restorations present. The risk factor "presence of a removable prosthetic appliance", which was shown to have a relatively strong effect, may also be a reflection of these compromised dentitions. In our cohort study (chapter 4), we included additional patient related variables such as caries

risk and general health. Within the multi variable cox regression, correcting for all known risk factors, restorations in young children performed best, which indicates restorations survival is not related to age per se, but rather to age related risk factors. Restorations placed in children are most frequently primary lesions. This could mean they are therefore less prone for failure compared to re-restoration cases.

Additionally, in chapter 4, there was a clear correlation between the diagnosis of restoration failure (caries or fracture) and the respective risk group (caries or parafunction). This indicates that the risk assessment performed by GDPs makes sense, and dentists are able to identify these risks, even though differences among dentists are very likely to occur. A recent clinical study on tooth wear patients, investigating parafunctional habits, showed fracture of a restoration as the predominant factor for its failure [15]. As evident from this study, and demonstrated by van de Sande et al. [13], there was an increased failure rate when both parafunctional habits and caries were present. Therefore, we would advise including risk assessment of patients in all prospective trials, including the diagnosis preceding placement of a restoration.

Tooth restoration related variables

At the tooth/restoration level, our retrospective studies (chapters 2 and 3) and cohort study (chapter 4) study showed that small restorations in vital premolar teeth performed best. This is in accordance with other studies [4, 16, 17]. Additionally, we found in chapter 3 that the number of surfaces influenced restoration survival in premolar teeth more than it did in molar teeth. Overall however, a much better restoration survival rate was found in premolars. The presence of an endodontic treatment in the tooth was found to be a major risk factor. However, in both our retrospective studies an under-identification of endodontically treated teeth must be assumed, as root canal treatments from the period previous to the observation period were not recorded in the dataset.

Posterior composite restorations showed the longest restoration survival in our retrospective studies, even higher than amalgam restorations. A similar result was previously reported only in low caries risk patients [3]. However, the effect of indication bias should be considered in this respect. Patient demand for replacing amalgam restorations for aesthetic reasons may have influenced this outcome, but perhaps more importantly, dentists may have chosen amalgam over composite only in specific situations. For instance, in cases where moisture control is problematic or patients exhibit poor oral hygiene.

Even assuming a comparable performance of these materials in this study is noteworthy; a recent Cochrane review reported superiority of amalgam over composite [18]. Interestingly, this Cochrane review was based solely on studies older than 11 years and risk assessment was not performed for these studies. In accordance with other clinical studies [19], glass-ionomer and compomer restorations showed a shorter survival compared to composite and amalgam restorations in our studies (Chapter 2 and 3). Again, indication differences must be assumed to have been a major factor of bias, as many glass-ionomer restorations will be temporarily placed, for instance in deep caries cases or after a root canal treatment. Moreover, these materials are likely to be used more in high risk patients and locations.

Statistics in longevity studies

For appropriate survival analysis of a population of restorations, it is necessary that for every restoration, the date of placement is available. The date of restoration failure or end of observation period for still functioning restorations (last check-up) is also required as an endpoint to the study. Kaplan Meier graphs can be used to explore restoration survival, by getting an impression at a glance. As an outcome measure, annual failure rate (AFR) is preferable, as it can be calculated for all observation times. Alternatively, median survival can be used but this can only be calculated after 50% of the restorations have failed (20). Mean Annual Failure Rates over 'x' years (AFR_x) should be calculated according to the formula: AFR (%) $= 1 - \sqrt[x]{y} * 100$, in which 'y' level of survival after 'x' years. Statistical tests

on Kaplan Meier data (e.g., Log-rank test) are inappropriate when a multi variable dataset is under investigation. When interested in calculating the effect of a single variable on restoration survival, a multiple Cox regression, with clustering data for patients with multiple restorations, should be conducted. When, as in our case, patients and all practices/operators contribute with multiple restorations, the method described by Chuang et al., to produce statistically valid standard errors for the estimates of survival, should be performed [21]. When applying multiple Cox regression models, the hazard ratios are all estimated as adjusted effect. That is, the effect of a specific single independent variable, while disconnecting it from all other independent variables in the model. Therefore the adjusted hazard ratios give the best estimate of the effect of independent variables and are considered as the highest standard of survival analysis. However, a condition for this is that the data is homogeneous.

In chapter 2 of this thesis we retrospectively described a large set of anterior and posterior restorations on several longevity influencing factors. We only performed a descriptive analysis on our data to get a general outcome of the entire dataset and to provide a first impression on the restorative work of Dutch GDPs. Given that anterior and posterior

restorations show different failure behaviour, it is not reliable to analyse this with a multi variable regression analysis. Caries risk, aesthetics, masticatory loading, trauma risk, all differ between anterior and posterior teeth. As a follow-up to chapter 2 and in order to perform a reliable multi variable cox regression analysis, we decided to write two separate papers in which the distinction is made between class II (posterior) (chapter 3) and class III/IV restorations [1].

In chapter 5 we investigated the influence of using different endpoint definitions and inclusion criteria in restoration longevity analysis, on the outcome expressed in Annual Failure Rate (AFR). Definitions of 'restoration failure' may vary and currently repair instead of replacement is considered a preferable treatment option for a defective restoration. Higher AFRs were found when the AFR was calculated over a longer period and when any new restorative intervention on a specific tooth is considered as a failure, which is often the case when insurance claims are used as data source (CD). Comparing results from longevity studies on direct restorations over the past ten years showed a wide variation in failure endpoints and AFRs. To improve quality of longevity studies and to be able to compare outcomes of longevity studies, it is important to describe the definitions of restoration failure unambiguously. In chapter 5 it is also demonstrated that Claims data which is often used in large studies, [22-24] leads to an under-estimation of restoration survival; especially as a repair can be considered as a prolonged longevity of the restoration instead of a failure. Therefore we would recommend that insurance companies that have access to a pool of claims data, take this into account as there may be a temptation to define survival rates of restorations that are 'lower than in clinical studies' as under-performance of dentists.

We did not investigate the effect of assessing failures based on either on dentists' clinical judgements or on a system of defined criteria [8, 25]. Rho et al. [26] previously studied this and showed clinically functioning restorations, when evaluated according to these criteria were considered as failed. Other studies investigating differences in clinical judgement between GDPs and experts suggest the use of calibrated criteria is not sufficient in obtaining unity of decision among experts [5, 27]. From an oral health care perspective, 'unacceptable' scores on items as colour, marginal adaptation, proximal contact often do not justify a restorative intervention and doing so would lead to overtreatment. For controlled trials evaluating a new restorative material, AFRs on actually repaired or replaced restorations should be used in the survival analysis, while the USPHS or FDI criteria can still be very useful in identifying differences between materials on a more detailed level in specific trials.

Decision making

As aforementioned, the decision of placing or replacing a restoration in private practice is based on the clinical expertise of the practitioner, rather than on a strict criteria system. Consequently, it seems that the dentist's intervention threshold plays an important role in restoration survival, as shown in chapters 2, 3 and 4. The observed operator differences may be related to operator skill, but it is likely that they are also related to practice organization, differing patient needs and demands and intervention choices by the dentists. Differences in treatment decisions between practitioners were shown to be considerable [9], and may be related to variation in survival times. As this is highly speculative, we aimed to map out operator intervention thresholds in chapter 6. It should be noted that the dentist population taking part in this questionnaire was different from and larger than the dentist population that provided the data for restoration survival in the other four chapters. We have already explained the reasons for this and want to iterate that the results from chapter 6 are not connected to the findings in the other chapters.

Within chapter 6, we aimed to explore a possible worldwide trend towards a more minimally invasive strategy concerning operative intervention on primary caries lesions. Previous results based on questionnaires designed by Espelid and Tveit [28, 29] were gathered and combined with the results from our questionnaire in the Netherlands. Although our response rate in our 2015 Dutch national questionnaire was low, which can be seen as a limitation, the data provided a general demographic-representative dataset. It proved difficult to extrapolate worldwide trends, due to limited and heterogeneous data; however, one trend was noted with regards to restorative material: composite resin has almost universally replaced amalgam as the preferred material for primary caries lesions. These findings are in accordance with other studies [30, 31].

An explanation for the scattered landscape in decision making, especially between countries is difficult to make as several factors which have not been previously investigated may be responsible for this. Differences in reimbursement systems, nationwide caries experience, the age of the dentist population, presence of a public health dental service or the dentist-patient ratio may be responsible for a delay in the implementation of new developments. Unsurprisingly, these differences also make it more difficult to extrapolate the outcomes of our longevity studies to other countries. For the Netherlands as well as other countries, there seems to be a clear need for further education of the profession towards a more conservative approach regarding restorative intervention, according to generally accepted guidelines. Our findings point to a more proactive approach by dentists. We also want to stress that for re-intervention decisions, the available evidence is even more limited. The decision to repair or replace seems to follow a growing minimally interventive concept [32].

Clinical implications for oral health care

This thesis is part of a research project looking at restorative practices of general dental practitioners in dentistry on a large scale. Besides the included studies, reports are published on the survival of crowns and anterior restorations, as well as the influence of repair on longevity, and the evaluation of re-restoration decisions [1, 6, 33, 34]. We think it is important to make some statements on restorative oral health care as we described and analysed this and make some recommendations for the future, for clinical research as well as for patient oral health.

1. The Longevity of restorations as placed by the group of dentists that participated in the PBRN network appears to be satisfactory. An estimated medium survival time for class II restorations of 12 years in a group of general practices is much better then reported in studies that are based on insurance claims [22-24]. We have shown in this thesis that insurance claim based data is likely to provide an underestimation of actual restoration survival rate. Moreover, this thesis and other related work [5] showed that the majority of restorative work is provided to people of high risk. In that high-risk group, caries and secondary caries is common and diagnoses as provided by a sample of the dentists of the network, assessed by experts confirms this [27]. The differences in restoration survival in high and low risk groups has been shown before and therefore, the outcome of longevity of restorative work should not be compared with the results of controlled trials that often exhibit annual failure rates of less than 1% [35] given the differences in the investigated population.
2. In this thesis, restorative dentistry in the real world was investigated. We therefore have to be careful when interpreting the results, as many grounds for bias are included, for example differences in risk-assessments, treatment choice, and handling EPFs. Indication bias, such as dentist preferences and patient demand for replacing amalgam restorations for aesthetic reasons, may have influenced our results. Moreover, the cohort study with a relatively short observation time may suffer from ''data pollution'', caused by temporary restorations and specific claims aspects, related to the reimbursement system in the Netherlands. Many of these variables were not controlled and will not be possible to control in practice based settings. In restorative dentistry, often the need for more randomized clinical trials is pointed out. However, one can doubt the relevance of controlled trials for oral health care of the general population, especially when risk patients are excluded and the diagnosis of the restoration is absent in the reports.

3. The large difference in restoration survival between practices is a remarkable finding which certainly needs to be investigated in the future. Especially the decision-making processes as mentioned in this thesis. Whilst this research is very appealing, it demands a large group of dentists with thorough EPF data. In this thesis, it was shown that a representative group of Dutch dentists, as well as dentists in other countries are still too invasive when it comes to intervening on primary caries lesions. Also for re-restoration decisions, especially regarding repair or replacement, differences in decision to intervene exist and could play a major role in restoration survival, although this is as yet unproven.
4. We used electronic patient files to collect the data for the studies. This showed that some information in the EPF regarding restorative treatments was not routinely noted in the files. Thanks largely to an innovative software company; we managed to implement changes to the EPF that allowed the input of specific restorative information as well as concomitant risk factors, to the benefit of both patients and dentists. The findings in Chapter 4 demonstrate the potential to use these risk factors as predictors for problems for the patient. Specific diagnoses such as caries could let the EPF warn the dentist for certain risks, and help the dentist to deliver a more personalized type of care for example by implementing individual prevention programmes.
5. In chapter 4 we were able to extract extensive data from the patient files. However, many EPFs were incomplete, resulting in missing data. Operators were invited and encouraged to complete EPFs with risk assessment, applied materials and diagnosis of the restoration. Unfortunately, the dentists did not always succeed in collecting all required data for all patients and treatments. The imputation of missing data as performed in this analysis was considered the best choice for dealing with this shortcoming. Performing analyses on complete cases only, is likely to result in exclusion bias and, especially in models with many independent variables, in loss of power. Particular attention to the completion of the electronic patient file will benefit both patients and future research.
6. In restorative dentistry, clinical studies aim to investigate the quality of restorations, preferably using highly detailed criteria like FDI or USPHS. These fixed criteria ignore the importance of the patients' perspective. When patients are satisfied with their imperfect restorations, including chips broken off, discolorations, marginal defects, without functional problems and a restoration still functioning, it can be considered as overtreatment if a dentist decides to replace a restoration. Therefore, it would be interesting to look at restorative work more from the patient's perspective.

7. The present study was carried out in the Netherlands, within the Dutch health care system. In the Netherlands, a fixed fee per item system exists and fees for large direct restorations are relatively modest and may not reflect the invested time, which may result in dentists claiming two smaller restorations in the same tooth instead of one large build-up. For other countries with other claim systems, this may result in different claim characteristics resulting in differences in claims data (CD) and actual survival (SUR) and success (SUC) data.
8. Risk assessment is important, but very difficult to implement and standardise in general practice. Data on caries experience, such as DMF-S or DMF-T, is not documented in the patient files and can therefore not be used. Within the PBR network, high caries risk was scored based on the presence of active lesions, number of new caries lesions (1 or more new caries lesions in the last year) and frequent sugar consumption. Low risk was assigned to patients without active lesions and new caries lesions (last restoration due to caries 2 or more years ago) and sufficient plaque control [36]. Due to lack of guidelines and protocols, the assessment of parafunctional habit score was based on the question: ''is there non-physiological wear visible on teeth or restorations?" We also considered indicators such as exposed dentin, distinctive wear facets, fractures of restorations or teeth and hypertrophic muscles of mastication. During meetings, we aimed to calibrate practitioners on risk assessment and we provided and discussed valuable background information and clinical cases to help standardize the risk assessment process. However, these decisions were still based on a subjective clinical impression. Given that both variables have a major influence on restoration survival; future research should focus on training and calibrating dentists on these diagnostic features.
9. The size of the defect matters; the larger the restoration, the shorter its survival. Whenever endodontic treatment is required, the prognosis of the tooth and restoration deteriorates substantially. These findings may further encourage dentists to apply a minimally invasive treatment approach. Consideration should be given to monitoring and repairing instead of replacing restorations, as while replacing might result in an improved aesthetic result in the short term, it could lead to earlier failure in the long term.

Conclusions of this thesis

- Practice Based Network GDPs placed restorations with a satisfactory longevity (mean AFR 4.6% over 10 years), but substantial differences in outcomes exist between practitioners.
- Individual patient risk factors such as; general health score, periodontal status, risk for parafunctional habits, and especially caries risk play a major role in restoration failure. To provide personalized oral health care, it is important to identify these risk factors and tailor treatment decisions to the risk profile. For clinical research, it seems imperative to record and include potential risk factors in future clinical studies.
- The extent of the restoration/defect matters: the number of surface a restoration encompasses influences restoration survival, a better survival for restorations in premolars was found, and presence of endodontic treatment was found to be a major risk factor for restoration failure.
- Distinguishing between success and survival for direct restorations leads to significantly different failure rates. Using these criteria unambiguously for future clinical studies would enable a better comparison of studies as well as demonstrating the impact of more conservative restorative intervention protocols on patient care.
- RCTs, using detailed criteria such as USPHS or FDI and often excluding high risk patients, can be very useful in identifying small differences between (new) materials on a more detailed level. However, results from this study design cannot be translated to general dental practice and should therefore not be normative.
- Large variations in restorative decision exist around the world when it comes to intervention in proximal and occlusal primary caries. Generally, dentists decide on operative interventions at too early a stage. Composite resin has almost completely replaced amalgam for restoring primary caries lesions.

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Chapter 8

Summary

Summary

The main objective of this thesis was to investigate the influence of possible risk factors at the practice/dentist level, the patient level and the tooth/restoration level on longevity of direct restorations. The extent to which each of these factors contributes to restoration survival was as of yet undetermined. A large database from the electronic patient files (EPF) of general practitioners (GDPs) in the practice-based research network Nijmegen enabled us to carry out further research with regards to these potential risk factors.

In this thesis we carried out a long-term retrospective practice-based study to investigate the longevity of direct restorations placed by a large group of GDPs and explore the effect of practice/operator, patient, and tooth/restoration related factors on restoration survival (Chapter 2). The influence of these possible risk factors on longevity of direct class II restorations were analysed, with a multiple Cox regression, in a long-term retrospective practice-based study (Chapter 3) and prospective cohort study (Chapter 4). In a retrospective methodology study (Chapter 5) we investigated the influence of using different endpoint definitions and inclusion criteria in longevity analysis on the outcome expressed in Annual Failure Rate. Finally, we explored decision making aspects of dentists, based on a questionnaire, to see if worldwide trends towards a more conservative minimally invasive treatment concept for primary caries restorative intervention existed (Chapter 6).

Chapter 1 describes an overview of different study designs, risk factors for restoration failure and survival rates from previous performed longevity studies. In addition, earlier and contemporary caries management for primary caries lesions and re-restoration cases were discussed.

The practice based study in **Chapter 2** evaluated the longevity of direct restorations placed by Dutch GDPs and explored the effect of practice/operator, patient, and tooth/restoration related factors on restoration survival. EPF from twenty-four general dental practices were used for collecting the data for this study. From the EPF, longevity of 359,548 composite, amalgam, glass-ionomer and compomer restorations placed in 75,556 patients by sixty-seven GDPs between 1996 and 2011 were analysed by Kaplan-Meier statistics. Wide variation in annual failure rate (AFR) existed between the different dental practices and restorations in elderly people (65 years and older) showed a shorter survival. Restorations in molar teeth, multi-surface restorations and restorations placed in endodontically treated teeth seemed to be more at risk for re-intervention. Several potential risk factors on practice/operator, patient, and tooth/restoration level have been identified and require further multivariable investigation.

In **Chapter 3** a subsequent retrospective practice-based study, based on the same study populations, described the clinical performance of class II restorations placed as part of routine everyday restorative care. In addition, the effect of practice, patient, and tooth/restoration related factors were investigated. From the EPF, survival rates of 222,836 composite, amalgam, glass-ionomer and compomer class II restorations placed in 61,121 patients were analysed by Kaplan-Meier statistics and a multiple Cox-regression. The investigated group of GDPs placed restorations with a satisfactory survival (mean AFR_{10}: 4.9%), although a wide variation in AFR existed. Restorations placed in young adults (21-30 years old) survived longest, while especially in children (5-12 years) and elderly (older than 71) a shorter restoration survival was observed. Confirmed by the multiple Cox-regression, restorations in molar teeth and multi-surface restorations are more at risk for re-intervention. However, restoration size has greater impact on restoration survival in premolar teeth than in molar teeth. An additional risk factor for restoration survival is an endodontic treatment.

The prospective cohort study in **Chapter 4** investigated the influence of a wider range of possible risk factors on practice, patient, tooth and restoration level on survival of class II restorations. EPF from 11 Dutch general practices were collected and 31,472 restorations placed between January 2015 and October 2017 were analysed. Kaplan Meier statistics were performed, AFRs were calculated, and included variables were assessed by multi-variable Cox regression analysis. A mean AFR_2 of 7.8% was found, but a wide variation in AFRs existed between the different operators varying between 3.6% and 11.4%. A plethora of patient related variables such as age, general health, periodontal status, caries risk and risk for parafunctional habits influenced restorations survival. Restorations in molar teeth, multi-surface restorations and restorations placed in endodontically treated teeth are at a higher risk for re-intervention. Restorations placed due to fracture were more prone to fail than restorations placed due to caries. Excluding patient related risk factors, remaining risk factors considerably changed in their effect and significance. The effect of operator, age of the patient and endodontic treatment increased. The effect of the diagnosis decreased and the Socio-Economic-Status became significant.

The retrospective methodology study in **Chapter 5** investigated the influence of using different definitions for restoration failure and inclusion criteria on restoration longevity expressed in AFR. EPF from fifteen general dental practices were used for collecting the data for this study. From the EPF, 321,749 composite restorations placed in 52,245 patients by forty-seven GDPs between January 2000 and December 2011 were included. Kaplan-Meier statistics were applied and mean AFRs over 2, 5 and 10 years were calculated. The effect on the AFR of using different levels of failure: based on Claims data (CD), Success

(SUC), Survival (SUR) and different inclusion criteria of tooth/restoration variables were reported. Highest AFRs were found for level CD, in which every intervention was considered as failure, and the lowest AFRs for level SUR in which repairs and an endodontic treatments were not considered as a failure. AFRs increased when the observation period prolonged especially for SUR, followed by SUC and CD. An overview of long-term survival studies showed a wide variation in study design, performed clinical examination (USPHS criteria or GDP), number of restorations included, description of restoration failure and found AFRs for CD, SUC and SUR.

Contemporary minimally invasive treatment concepts for restorative treatment of primary caries lesions includes both a delayed moment of intervention and smaller sized preparations, restricted to removal of carious tissue. The study in **Chapter 6** investigated whether these concepts have resulted into trends toward a more conservative choice, regarding treatment thresholds and restorative techniques. Results from a recent Dutch questionnaire and previous conducted questionnaires were collected and analysed. A worldwide trend towards more minimal invasive strategies in operative treatment of caries lesions could not be observed, neither for initiation of operative treatment nor for preparation techniques. From the Dutch national survey it could be concluded that operators that intervene in an earlier stage of approximal lesions, also intervene in an earlier stage of occlusal caries. Generally, it could be concluded that dentists worldwide still tend to intervene operatively at a too early caries stage, although variations exists between countries. A worldwide shift could be observed in the applied restorative material, as composite resin has almost completely replaced amalgam for restoring primary caries lesions.

Finally, **in Chapter 7**, the available literature, results, limitations, and conclusions from our studies were further discussed, along with avenues for future research. Based on this thesis we conclude that many practice/operator, patient and tooth/restoration related variables are influencing restoration survival and a large variation in restoration survival exist between GDPs. To provide personalized oral health care, it is important to identify patient related risk factors and tailor treatment decisions to the risk profile. For clinical research, it seems imperative to record and include potential risk factors in future clinical studies.

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Chapter 9

Samenvatting

Samenvatting

De belangrijkste doelstelling van dit proefschrift was om de invloed van mogelijke praktijk/operateur-, patiënt- en element/restauratie gerelateerde risicofactoren op de levensduur van directe restauraties te onderzoeken. De mate waarin elk van deze factoren bijdraagt aan de overleving van restauraties was tot nu toe onduidelijk. Een grote database van elektronische patiëntendossiers (EPDs) van algemeen practici binnen het praktijkgerichte onderzoeksnetwerk Nijmegen heeft ons in staat gesteld deze onderzoeksvragen te beantwoorden.

In dit proefschrift hebben we een lange termijn retrospectieve praktijkgerichte studie uitgevoerd om de levensduur van directe restauraties van een grote groep van algemeen practici te onderzoeken en het effect van praktijk/operateur, patiënt en element/restauratie gerelateerde factoren te verkennen (Hoofdstuk 2). De invloed van deze mogelijke risicofactoren op de levensduur van directe klasse II restauraties werd geanalyseerd, met een meervoudige Cox-regressie, in een lange termijn retrospectieve studie (Hoofdstuk 3) en prospectieve cohort studie (Hoofdstuk 4). In een retrospectieve methodologische studie (Hoofdstuk 5) onderzochten we de invloed van het gebruik van verschillende definities van restauratie falen en inclusiecriteria op de uitkomst van de levensduuranalyse uitgedrukt in het jaarlijks faalpercentage (JFP). Ten slotte hebben we op basis van een vragenlijst de besluitvormingsaspecten van tandartsen onderzocht. Hierin werd gekeken of er wereldwijde trends waarneembaar zijn in de richting van een conservatief minimaal invasief behandelconcept voor primaire cariës (Hoofdstuk 6).

Hoofdstuk 1 beschrijft een overzicht van verschillende onderzoeksopzetten, risicofactoren voor restauratie falen en overlevingspercentages van eerder uitgevoerde levensduur studies. Daarnaast werden eerdere en hedendaagse behandelconcepten voor primaire cariëslaesies en herrestauratie besproken.

De praktijkgerichte studie in **Hoofdstuk 2** evalueerde de levensduur van directe restauraties geplaatst door Nederlandse algemeen practici en onderzocht daarnaast het effect van de praktijk/operateur, patiënt en element/restauratie gerelateerde factoren op de overleving. EPDs van vierentwintig algemene tandartspraktijken werden gebruikt voor het verzamelen van de gegevens voor deze studie. Vanuit de EPDs, werd de levensduur van 359.548 composiet-, amalgaam-, glasionomeer- en compomeer restauraties, geplaatst in 75.556 patiënten door zevenenzestig algemeen practici tussen 1996 en 2011, bepaald door middel van Kaplan-Meier statistiek. Er bestond een grote variatie in JFP tussen de verschillende tandartspraktijken en restauraties bij ouderen (65

jaar en ouder) vertoonden een kortere overleving. Restauraties in molaren, restauraties met meerdere behandelde vlakken en restauraties geplaatst in endodontisch behandelde elementen lopen meer risico op een restauratieve interventie. Verschillende potentiële risicofactoren op het niveau van de praktijk/operateur, patiënt en element/restauratie zijn geïdentificeerd en vereisen verder multivariabel onderzoek.

Hoofdstuk 3 beschreef een daaropvolgende retrospectieve praktijkgerichte studie, gebaseerd op dezelfde studiepopulaties, de klinische prestaties van klasse II restauraties die werden geplaatst als onderdeel van de dagelijkse routinematige verleende zorg. Daarnaast werd het effect van praktijk/operateur-, patiënt- en element/restauratie gerelateerde factoren op de overleving onderzocht. Vanuit de EPDs werden overlevingspercentages van 222.836 composiet-, amalgaam-, glasionomeer- en compomeer klasse II restauraties, geplaatst bij 61.121 patiënten, geanalyseerd met Kaplan-Meier statistiek en een multipele Cox-regressie. De onderzochte groep van algemeen practici plaatste restauraties met een goede overleving (gemiddeld JFP_{10}: 4,9%), hoewel er een grote variatie bestond in JFPs tussen de verschillende operateurs. Restauraties geplaatst bij jong volwassenen (21-30 jaar oud) overleefden het langst, terwijl vooral bij kinderen (5-12 jaar) en ouderen (ouder dan 71 jaar) een kortere restauratie overleving werd waargenomen. Bevestigd door de meervoudige Cox-regressie, lopen restauraties in molaren en restauraties met meerdere behandelde vlakken meer risico op een restauratieve interventie. De grootte van de restauratie heeft echter een grotere impact op de overleving van restauraties in premolaren dan van restauraties in molaren. Extra risicofactor voor restauratie overleving is een endodontische behandelding.

De prospectieve cohort studie in **Hoofdstuk 4** onderzocht de invloed van een groter bereik van mogelijke risicofactoren, op praktijk/operateur-, patiënt- en element/restauratie niveau, op de overleving klasse II restauraties. Vanuit de EPDs van 11 algemene tandartspraktijken werden 31.472 restauraties, geplaatst tussen januari 2015 en oktober 2017, geanalyseerd. Na de uitvoering van Kaplan Meier stastistiek, werden JFPs berekend en de geincludeerde variabelen geanalyseerd met een multipele Cox-regressie. Er werd een gemiddeld JFP_2 van 7,8% gevonden, maar er bestond een grote variatie in JFPs tussen de verschillende operateurs, variërend tussen 3,6% en 11,4%. Verschillende patiëntgerelateerde variabelen zoals leeftijd, algemene gezondheidstoestand, parodontale status, cariësrisico en het risico op parafunctioneel gedrag, beïnvloedde de overlevingsduur van een restauratie. Restauraties in molaren, restauraties met meerdere behandelde vlakken en restauraties in endodontisch behandelde elementen lopen een groter risico op een restauratieve interventie. Restauraties welke geplaatst werden als gevolg van fractuur hebben een hoger risico op een nieuwe interventie dan restauraties

die geplaatst werden als gevolg van cariës. Wanneer de patiëntgerelateerde risicofactoren geëxcludeerd werden uit de regressie analyse, veranderden de resterende risicofactoren in hun effect en significantie. Het effect van de operateur nam toe, evenals het effect voor de leeftijd van de patiënt en de aanwezigheid van een endodontische behandeling. Het effect van de diagnose nam af en de sociaaleconomische status werd significant.

Het retrospectieve methodologieonderzoek in **Hoofdstuk 5** onderzocht de invloed van het gebruik van verschillende definities voor restauratie falen en inclusiecriteria op de levensduur uitgedrukt in JFP. EPDs van vijftien algemene tandartspraktijken werden gebruikt voor het verzamelen van de gegevens voor deze studie. Vanuit de EPDs werden 321.749 composietrestauraties, geplaatst bij 52.245 patiënten door zevenenveertig algemeen pracitici, tussen januari 2000 en december 2011 geincludeerd. Kaplan-Meier statistiek werd toegepast en het JFP over 2, 5 en 10 jaar werd berekend. Het effect op het JFP door het gebruik van verschillende niveaus van falen: op basis van declaratie gegevens (DG), succes (SUC), overleving (SUR) en verschillende inclusiecriteria van element/ restauratie variabelen werden gerapporteerd. De hoogste JPFs werden gevonden op het niveau DG, waarbij elke interventie als falen werd beschouwd, en de laagste JFPs voor niveau SUR waarbij reparaties en een endodontische behandelingen niet als falen werden beschouwd. JFPs namen toe wanneer de observatieperiodes langer werden, vooral voor SUR, gevolgd door SUC en CD. Een overzicht van lange termijn overlevingsstudies toonde een grote variatie in onderzoeksopzet, restauratie beoordeling (USPHS criteria of algemeen practici), aantal geincludeerde restauraties, beschrijving van restauratie falen en gevonden JFPs voor CD, SUC en SUR.

Hedendaagse minimaal invasieve behandelingsconcepten voor de restauratieve behandeling van primaire cariëslaesies omvatten zowel een later moment van restauratief ingrijpen, als een preparatievorm beperkt tot het slechts verwijderen van carieus weefsel. In **Hoofdstuk 6** werd onderzocht of deze concepten hebben geleid tot trends in de richting van conservatievere behandelingsdrempels en restauratietechnieken. Hierbij werden de resultaten van een recente Nederlandse vragenlijst en de resultaten van eerder uitgevoerde vragenlijstenonderzoeken verzameld en geanalyseerd. Een wereldwijde trend naar minimaal invasieve strategieën, bij de restauratieve behandeling van cariëslaesies, kon niet worden waargenomen, noch voor de behandelingsdrempel, noch voor de restauratietechnieken. Uit de Nederlandse nationale enquête kon worden geconcludeerd dat operateurs die in een vroeger stadium van approximale laesies restauratief ingrijpen, ook in een vroeger stadium van occlusale cariës interveniëren. Ondanks het feit dat er verschillen tussen landen bestaan, kon er over het algemeen geconcludeerd worden dat tandartsen over de hele wereld nog steeds de neiging

hebben om in een te vroeg stadium van het cariës proces restauratief in te grijpen. Er kon echter wel een wereldwijde verschuiving waargenomen worden in de toepassing van restauratiematerialen, waarbij composiet amalgaam bijna volledig heeft vervangen voor het herstellen van primaire cariëslaesies.

Ten slotte werd in **Hoofdstuk 7** de bestaande literatuur, de resultaten, de beperkingen en de conclusies van onze studies besproken, eveneens als de mogelijkheden voor toekomstig onderzoek. Op basis van dit proefschrift concluderen we dat veel praktijk/operateurs-, patiënt- en element/restauratie gerelateerde variabelen de overleving van restauraties beïnvloeden en er een grote variatie in restauratie overleving bestaat tussen algemeen practici. Om gepersonaliseerde mondzorg te bieden, is het belangrijk om patiëntgerelateerde risicofactoren te identificeren en behandelbeslissingen aan te passen aan het risicoprofiel van de patiënt. Voor klinisch onderzoek lijkt het noodzakelijk om de potentiële risicofactoren op te nemen in toekomstige klinische studies.


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Lieve Loes, ongelofelijk hoe snel goede vriendschappen kunnen ontstaan. Na de epische vierdaagse feesten van vorig jaar, hebben de mooie en hilarische momenten zich op hoog tempo opgestapeld. Naast de verschillende feestjes, festivals en vakanties, was het ook altijd heel relaxed om samen in ''Huize Smaske" te borrelen en te gamen. Pas goed op onze crib en geniet er ook van. Loes, je bent top en ik ga je gezelligheid zeker missen in Oslo.

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Dear Erasmus friends, dear Abdi, Dimitry, Pilvi, Ana, Ema, Anna, Sofia and Bea, thank you for the great memories we share. Our yearly reunion trips in Stockholm, Portugal, Iceland, the Netherlands and London were awesome and I hope we can keep continuing this tradition. Abdi, you slight old dog, thank you for correcting some of my papers and sharing your great sense of humor. We all hope to stay in touch with you, also after the Brexit;)

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Curriculum Vitae

Mark Laske werd op 15 juli 1989 geboren te Lelystad. Na het behalen van zijn gymnasiumdiploma aan het Almere College te Dronten startte hij met zijn studie Tandheelkunde aan de Radboud Universiteit Nijmegen. Gedurende zijn studie heeft hij diverse nevenfuncties vervuld, waaronder in 2011-2012 Assessor I van de Tandheelkundige FaculteitsVereniging Nijmegen. Zijn wetenschappelijke stage liep hij op de afdeling Preventie en Curatieve Tandheelkunde (PCT) van de faculteit Tandheelkunde (hoofd: Prof. Dr. M.C.D.N.J.M. Huysmans). Na het behalen van het tandartsdiploma in 2013, heeft hij vervolg gegeven aan zijn onderzoeksstage en is hij gestart met zijn promotietraject. Naast zijn promotietraject is hij van 2013 tot 2018 verbonden geweest aan het Centrum voor Bijzondere Tandheelkunde van het Radboudumc op het gebied van de Maxillofaciale Prothetiek. Daarnaast werkt hij binnen verschillende algemene tandartspraktijken in Dronten, Lelystad en Beek.

Per 1 april 2019 is hij aangesteld als post-doc bij de afdeling Tandheelkunde van het Radboudumc waar hij zijn Practice Based Research zal voortzetten en zich zal gaan verdiepen in Health Economics. Na zijn verdediging vertrekt hij naar Scandinavië, waar hij het eerste jaar van zijn post-doc verbonden zal zijn aan de Universiteit van Oslo.

List of publiations

Related to this Thesis

Laske M, Opdam NJM, Bronkhorst EM, Braspenning JCC, Huysmans MCDNJM. Longevity of direct restorations in Dutch dental practices. Descriptive study out of practice based research network. Journal of Dentistry 46 (2016) 12-17

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Submitted

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Collares K, Correa MB, **Laske M**, Kramer E, Reiss B, Moraes RR, Huysmans MCDNJM, Opdam NJM. A practice-based research network on the survival of ceramic inlay/onlay restorations. Dental material 32 (2016) 687-694.

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Koninklijke Nederlandse Maatschappij ter bevordering der Tandheelkunde (KNMT)

Nederlandse Wetenschappelijke Vereniging van Tandartsen (NWVT)

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Nederlandse Vereniging voor Gnatologie en Prothetische Tandheelkunde (NVGPT)

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